

Put It on the Board

Pathology, lab organizations endorse use of CKD-EPI 2021 race-free equations

March 2022—The CAP was one of eight pathology and laboratory organizations to endorse in a joint statement the use of the CKD-EPI 2021 race-free equations for calculating estimated glomerular filtration rate. The others are the Academy of Clinical Laboratory Physicians and Scientists, American Association of Clinical Chemistry, American Society for Clinical Pathology, Association of Pathology Chairs, Clinical Laboratory Management Association, National Independent Laboratory Association, and Society of American Federated Medical Laboratory Scientists (the views of the SAFMLS do not represent the views of the U.S. government). Following is the statement they released on Jan. 31.

Serum creatinine with estimated glomerular filtration rate (eGFRcr) is frequently measured and reported by United States clinical laboratories. This test is included in the basic metabolic, comprehensive metabolic, and renal function panels, and the Kidney Profile.¹ The eGFRcr and urine albumin to creatinine ratio (uACR) are currently the primary tests used in clinical practice to assess kidney function, diagnose kidney disease, determine the severity of kidney disease, and monitor progression. The eGFRcr is also used to inform treatment decisions, including medication dosing, timing of referral to nephrology, and preparing for kidney replacement therapies.

More than 37 million adults in the U.S. have kidney disease. Of these, almost 90 percent are unaware that they have it. A disproportionate number of people living with kidney disease are from groups that routinely face health disparities and inequities in health care delivery, including Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Asian Americans, and Native Hawaiians or other Pacific Islanders.

The two equations most used to calculate eGFRcr in the United States, the Modification of Diet in Renal Disease (MDRD) Study and the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equations, include a race coefficient. As race is a subjective, social construct, the National Kidney Foundation (NKF) and the American Society of Nephrology (ASN) established a task force in 2020 to reassess the inclusion of race in diagnosing kidney diseases in the United States. The NKF-ASN Task Force employed a holistic approach incorporating input from the medical community and patients to identify an approach that balanced social justice with scientific rigor.

The final NKF-ASN Task Force report recommends:

- The use of the CKD-EPI 2021 eGFR creatinine equation for calculating eGFRcr in adults.^{2,3} This new equation is recommended because a race coefficient is not included in its computation and reporting. The CKD-EPI 2021 eGFR creatinine equation included diversity in its development and does not disproportionately affect any one group.³
- National efforts are also underway to facilitate increased, routine, and timely use of cystatin C (CPT 82610), especially to further evaluate eGFRcr in adults who are at risk for or have chronic kidney disease, or in individuals with abnormally high or low muscle mass. The CKD-EPI

2021 eGFR using creatinine and cystatin C (eGFRcr-cys) is more accurate, more closely approximates measured GFR, and supports better clinical decisions than either marker alone.^{2,3}

The nation's laboratories are working to employ a consistent, standardized approach for estimating GFR to improve testing for kidney diseases. Together the laboratory organizations (named above) endorse the national implementation of the CKD-EPI 2021 creatinine and creatinine-cystatin C equations for the estimation of glomerular filtration rate.

1. Choosing Wisely, an initiative of the ABIM Foundation. American Society of Clinical Pathology. Recommendation for Chronic Kidney Disease Testing. 2018 (bit.ly/2SFSz3u).
2. Delgado C, Baweja M, Crews DC, et al. A unifying approach for GFR estimation: recommendations of the NKF-ASN Task Force on reassessing the inclusion of race in diagnosing kidney disease. *Am J Kidney Dis*. doi:10.1053/j.ajkd.2021.08.003.
3. Inker LA, Eneanya ND, Coresh J, et al. New creatinine- and cystatin C-based equations to estimate GFR without race. *N Engl J Med*. 2021. doi:10.1056/NEJMoa2102953.

Leica, Leap Therapeutics partner on CDx

Leica Biosystems has entered into an agreement with Leap Therapeutics to develop a companion diagnostic to detect Dickkopf-related protein 1 (DKK1). The assay will be used to support clinical development of Leap's anti-DKK1 cancer therapy, DKN-01, which is being studied now in clinical trials.

Overexpression of DKK1 is associated with poor survival in cancer patients. Leap is studying the DKN-01 drug as part of a combination therapy regimen in a phase two clinical trial in patients with gastric or gastroesophageal junction cancer.

The assay Leica will develop will use RNAscope technology from Bio-Techne on the Bond-III automated staining system, which allows for detection of DKK1 with high sensitivity and specificity, Leica says, to help identify patients most likely to benefit from DKN-01 treatment.

Sema4 to acquire GeneDx

Sema4, an AI-driven genomic and clinical data intelligence platform company, and Opko Health signed a definitive agreement for Sema4 to acquire Opko's wholly owned subsidiary GeneDx.

Sema4 will acquire GeneDx for \$150 million in cash and 80 million shares of Sema4 (the deal includes an additional \$150 million in revenue-based milestones over the next two years). The deal is expected to close in the second quarter.