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National Kidney Foundation, American Society for Clinical Pathology, Leading Laboratories and Clinical Laboratory Societies Unite to Diagnose Chronic Kidney Disease

New "Kidney Profile" Simplifies Diagnostic Tests with Aim to Help Detect Disease Early

New York, NY—February 21, 2018—The National Kidney Foundation (NKF), the American Society for Clinical Pathology (ASCP) and the nation's leading laboratories and clinical laboratory societies have announced a new collaboration to remove barriers to testing for chronic kidney disease (CKD). The new collaboration will help standardize the tests used to detect CKD, improve comparison of test results between laboratories, increase early recognition of the disease and promote patient awareness of the condition. Almost 75 million Americans are at risk for developing chronic kidney disease as a result of hypertension or diabetes. Approximately 30 million Americans have CKD, but only about 3.6 million are currently aware that they have this condition. CKD progression can be slowed or halted if the disease, which often has no symptoms, is caught in its early stages.

The collaboration announced today is believed to be the first to combine the resources and talents of leading clinical laboratory societies, multiple laboratory providers, and a patient advocacy group to advance improvements in CKD laboratory testing. ARUP Laboratories, BioReference Laboratories, Inc., LabCorp, Mayo Medical Laboratories, Memorial Sloan Kettering Cancer Center, Quest Diagnostics and Sonic Healthcare USA have aligned with the initiative recommendations to improve CKD screening, diagnosis and care management. Any interested laboratory can join the collaboration and execute the suggested changes.

A component of this new collaboration is the recommendation of a new test profile for CKD assessment and diagnosis. This new CKD "Kidney Profile" follows evidence-based clinical practice guidelines, which recommend two tests for CKD assessment. Laboratories adopting the "Kidney Profile" will simplify ordering of the tests

needed to detect and diagnose CKD by pairing them together under one heading on the laboratory requisition form or electronic health record order. Such streamlining of CKD test ordering could help to eliminate the need to search for each test separately and increases the ease of monitoring results. The "Kidney Profile" also makes it easier for people at risk for CKD to better understand and track their health.

"Diagnosing kidney disease early is critical to improving long-term health in patients; this was the impetus for uniting the laboratory community around solving this problem," said Joseph Vassalotti, MD, Chief Medical Officer, National Kidney Foundation. "The new 'Kidney Profile' makes it easier for primary care physicians to determine if an at-risk patient has kidney disease, as it contains all the critical tests in one easy-to-order place."

Currently, 94% of patients with high blood pressure (hypertension) and 61% with diabetes are <u>not receiving both</u> <u>tests necessary to detect and assess chronic kidney disease</u> as recommended by clinical practice guidelines,¹ despite these being the top two risk factors for developing chronic kidney disease.

"More than 30 million Americans are estimated to be living with CKD, but most aren't aware of their status," said Lee Hilborne, MD, MPH, Past President and Chair of the Appropriate Test Utilization Committee, ASCP. "Once diagnosed, too many patients are in the later stages of the disease or have kidney failure, which requires dialysis or transplantation. Screening for CKD in the primary care setting may help more patients be diagnosed in early stage disease and ultimately improve outcomes."

The new "Kidney Profile" combines the estimated glomerular filtration rate (eGFR), which assesses kidney function, and urine albumin-creatinine ratio (ACR), which assesses kidney damage. Both are used to test for and diagnose CKD in primary care settings. Specifically, the "Kidney Profile" combines 1) eGFR (serum creatinine with eGFR: CPT 82565) and 2) urine ACR (albumin, urine [e.g., microalbumin], quantitative: CPT 82043 plus urine creatinine: CPT 82570). People living with CKD have an elevated risk for cardiovascular disease. This combination of eGFR and ACR testing has been shown to be a strong predictor of both cardiovascular mortality and kidney failure risk.

NKF and ASCP also recommend that laboratories use the same equation to estimate GFR and rename the microalbumin test to one that more accurately reflects what it is measuring -- albumin-creatinine ratio, urine. Standardized ACR reporting using milligrams per gram will make it easier for clinicians to compare results received from different labs.

NKF sincerely thanks ASCP for its partnership in developing the related materials for patients and professionals, and the following organizations for working with NKF to improve assessment of individuals at risk for kidney disease: American Association of Bioanalysts, American Association for Clinical Chemistry, American Clinical Laboratory Association, ARUP Laboratories, BioReference Laboratories, Inc., Clinical Laboratory Management Association, LabCorp, Mayo Medical Laboratories, Memorial Sloan Kettering Cancer Center, National Independent Laboratory Association, Quest Diagnostics and Sonic Healthcare USA.

Healthcare professionals can learn more about the "Kidney Profile" by visiting www.ascp.org/kidneyprofile. A fact sheet for doctors to share with their patients is available. This brochure explains what kidneys do, how to keep kidneys healthy and what tests determine if kidneys are working properly.

Kidney Disease Facts

30 million American adults are estimated to have <u>chronic kidney disease</u>—and most aren't aware of it. One in 3 American adults are at risk for chronic kidney disease. Risk factors for kidney disease include diabetes, high blood pressure, heart disease, obesity and family history of kidney failure. People of African American, Hispanic, Native American, Asian or Pacific Islander descent are at increased risk for developing the disease. African Americans are 3 times more likely than Whites, and Hispanics are nearly 1.5 times more likely than non-Hispanics to develop end stage renal disease (kidney failure).

National Kidney Foundation

The National Kidney Foundation (NKF) is the largest, most comprehensive and longstanding organization dedicated to the awareness, prevention and treatment of kidney disease. For more information about NKF visit www.kidney.org.

American Society for Clinical Pathology

Founded in 1922 in Chicago, ASCP is a medical professional society with more than 100,000 member board-certified anatomic and clinical pathologists, pathology residents and fellows, laboratory professionals and students. ASCP provides excellence in education, certification and advocacy on behalf of patients, pathologists and laboratory professionals. To learn more, visit www.ascp.org. Follow us on Twitter at www.twitter.com/ascp_chicago and connect with us on Facebook at www.facebook.com/ASCP.Chicago.

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1. Inker, L.A., et al., KDOQI US commentary on the 2012 KDIGO clinical practice guideline for the evaluation and management of CKD. *American Journal of Kidney Diseases*. 2014; 63(5): 713-35.