

RENALYTIX AI

RenalytixAI Announces KidneyIntelX Validation Study Accepted for Publication in American Society of Nephrology Journal Kidney360

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NEW YORK, July 1, 2020 /PRNewswire/ -- [Renalytix AI plc](#) (LSE: RENX), an artificial intelligence-enabled in vitro diagnostics company, focused on optimizing clinical management of kidney disease to drive improved patient outcomes and lower healthcare costs, today announced that results of a clinical validation study have undergone peer-review and have been accepted for publication in the American Society of Nephrology Journal, *Kidney360*.

The published manuscript titled, "*Validation of a machine-learning-derived prognostic test (KidneyIntelX) integrating biomarkers and EHR data to predict longitudinal-kidney outcomes*," is available through the Early Access format of the American Society of Nephrology journal, *Kidney360*: <https://kidney360.asnjournals.org/content/early/2020/06/29/KID.0002252020>

The study provides details of the primary analysis and numerous sub-analyses which demonstrate robust performance of the *KidneyIntelX* test in the two clinical contexts. These validation results complement the multi-center validation study in patients with prevalent diabetic kidney disease previously reported (<https://www.medrxiv.org/content/10.1101/2020.06.01.20119552v3>). These findings were reported in part previously in BioRxiv, the preprint server for biology, operated by ColdSpring Harbor Laboratory (bioRxiv 587774; doi: <https://doi.org/10.1101/587774>),

The primary objective of this validation study was to demonstrate if the *KidneyIntelX* artificial intelligence-enabled algorithm was able to predict which patients are at highest risk of adverse kidney outcomes with more accuracy than the existing standard of care. The optimized *KidneyIntelX* assay, combining sTNFR1, sTNFR2 and KIM-1 together with clinical data from electronic health records, achieved a PPV of 62% in the top 15% highest risk of the T2D population vs. 46% as classified by the clinical model ($p < 0.01$ for comparison). Likewise, in the Apolipoprotein L1 high-risk (*APOL1*) genotype cohort, the PPV of KidneyIntelX was 62% in the top 15% highest risk of *APOL1*-HR population vs. PPV of 39%, as classified by the clinical model, ($p < 0.01$ for comparison). The study included 871 patients with Type 2 diabetes and 498 patients of African Ancestry with *APOL1* high-risk genotypes (i.e., one copy of the genetic risk variant on both chromosomes).

Better risk stratification tools are needed to facilitate the application of novel treatments for DKD and CKD in patients with relatively preserved kidney function. Earlier identification of high-risk patients should allow for the improved ability to slow progressive decline in kidney function before patients reach late stages of CKD and need a kidney transplant or dialysis.

About Kidney Disease

Kidney disease is now recognized as a public health epidemic affecting over 850 million people globally. The Centers for Disease Control and Prevention ("CDC") estimates that 15% of US adults, or 37 million people, currently have CKD. Further, the CDC reports that 9 out of 10 adults with CKD do not know they have it and 1 out of 2 people with very low kidney function who are not on dialysis do not know they have CKD*. Kidney disease is referred to as a "silent killer" because it often has no symptoms and can go undetected until a very advanced stage. Each year kidney disease results in more deaths than breast or prostate cancer. Every day, 13 patients in the United States die while waiting for a kidney transplant.

* <https://www.cdc.gov/kidneydisease/publications-resources/2019-national-facts.html>

About RenalytixAI

RenalytixAI is a developer of artificial intelligence-enabled clinical in vitro diagnostic solutions for kidney disease, one of the most common and costly chronic medical conditions globally. RenalytixAI's products are being designed to make significant improvements in kidney disease diagnosis, transplant management, clinical care, patient stratification for drug clinical trials, and drug target discovery. For more information, visit www.renalytixai.com.

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