

# RENALYTIX AI

## KidneyIntelX™ receives New York State approval to commence commercial testing

June 12, 2020

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[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, announces that it has received a clinical laboratory permit from the New York State Department of Health (NYS DOH) to provide commercial testing of *KidneyIntelX™*. The permit was granted following an extensive review by a panel of NYS DOH scientists and external reviewers of the analytical and clinical validation results for *KidneyIntelX*. Additionally, officials from the NYS DOH successfully completed an inspection of the RenalytixAI New York laboratory as part of this process, with no findings reported.

### Highlights

- *Approval to commence commercial testing issued by New York State Department of Health's Clinical Laboratory Evaluation Program*
- *RenalytixAI now moving to complete full KidneyIntelX commercial integration with Mount Sinai Health System with patient testing to begin in Q3 2020*
- *With licensed CLIA commercial laboratories in Utah and New York, RenalytixAI can now provide KidneyIntelX testing services in 47 states with expected licensure for California, Maryland and Pennsylvania in 2020*

Effective immediately, *KidneyIntelX* may now be used to report risk assessment results for fast-progressing kidney disease and future kidney failure for patients with Type 2 diabetes and chronic kidney disease. With this approval, RenalytixAI will move to complete its full commercial launch of *KidneyIntelX* with Mount Sinai Health System and expects to begin reporting patient results in the third quarter of this calendar year.

*KidneyIntelX* is intended to be used in conjunction with clinical evaluation as an aid in the risk assessment of progressive kidney function decline within a period up to five years. A progressive decline in kidney function occurs when one or more of the following conditions are observed:

- Rapid Kidney Function Decline (RKFD) in eGFR slope of  $\geq 5$  ml/min/1.73m<sup>2</sup>/year;
- a sustained decrease in eGFR  $\geq 40\%$  confirmed at least 3 months apart; or
- kidney failure, defined by sustained eGFR  $< 15$  ml/min/1.73m<sup>2</sup>, initiation of long-term dialysis or kidney transplantation.

As announced on 10 June, a recent expanded multi-centre validation study demonstrated that *KidneyIntelX* can identify patients at the highest risk of progressive decline in kidney function in early stage diabetic kidney disease with higher accuracy than existing care methods.

The New York State Department of Health's Clinical Laboratory Evaluation Program (CLEP) regulates and oversees clinical diagnostic laboratories that test biological specimens from New York State residents. The CLEP seeks to ensure the accuracy and reliability of test results in clinical laboratories located within the state or that accept specimens from New York State residents.

While approval for *KidneyIntelX* patient testing has been granted for an indefinite period, it is subject to ongoing compliance with New York Department of Health regulations and standards. NYS DOH reserves the right to request more information and to withdraw the approval should evidence of non-compliance be identified.

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### Enquiries

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## **About Kidney Disease**

Kidney disease is now recognised as a public health epidemic affecting over 850 million people globally. The Centers for Disease Control estimates there that 15% of United States adults or 37 million people currently have kidney disease. It is reported that 9 out of 10 adults with chronic kidney disease 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 kills more people than breast and prostate cancer. Every day 13 patients die in the United States 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. The Company’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 [renalytixai.com](http://renalytixai.com)