



## KidneyIntelX™ included in Final KDIGO 2024 Clinical Guideline for Chronic Kidney Disease (CKD)

March 14, 2024

### Guidelines highlight the importance of risk prediction and personalized treatment to reduce risk

LONDON and SALT LAKE CITY, March 14, 2024 (GLOBE NEWSWIRE) -- Renalytix plc (NASDAQ: RNLX) (LSE: RENX) (Renalytix) announces that the KidneyIntelX *In-Vitro Diagnostic* test has been included in the final KDIGO (Kidney Disease Improving Global Outcomes) [2024 Clinical Practice Guideline](#) for the Evaluation and Management of Chronic Kidney Disease (CKD), published on March 13, 2024. In the release of the new guideline, timed to coincide with World Kidney Day on March 14, the KDIGO committee highlighted the role of risk prediction in guiding care for patients. In this context, KidneyIntelX is recommended for use as an externally validated tool for predicting disease progression in people with CKD stages G1-G3.

The Guideline Work Group recognized that the progression of CKD can occur at all stages, and that in earlier stages of disease (G1–G3), understanding the risk of 40% decline in kidney function over a short term 5 years, as per the indicated use of KidneyIntelX, is important for guiding early intervention, particularly in people at intermediate or high risk for progression. Renalytix received FDA de-novo marketing authorization for kidneyintelX.dkd in June 2023 for use in assessment of the risk of progressive decline in kidney function in patients with CKD stages G1-G3 and Type 2 Diabetes.

Subsequent to the release of the draft content of this updated guideline in July 2023, further evidence has been published from clinical utility and outcomes studies with a current enrollment of more than 9,000 patients with Type 2 Diabetes and CKD G1-G3. In January 2024, published outcomes data from an analysis of more than 2,500 patients with one year of follow-up demonstrated that providing clinicians access to KidneyIntelX risk assessment to inform care was associated with clinical actions that resulted in sustained reduction in eGFR decline, improved diabetes management and improved cardiovascular health.

**In the KDIGO announcement of the publication of the 2024 CKD guideline, Adeera Levin MD, one of the Guideline Committee Co-Chairs said,** “Recent advancements in GFR evaluation, risk prediction, and the arrival of novel treatments are poised to enhance CKD prognosis and management. We also hope the guideline’s emphasis on multidisciplinary teamwork, patient engagement, and a holistic, evidence-based approach to care will help catalyze positive change, resulting in more coordinated CKD care management worldwide. By integrating the latest evidence and expert consensus, we aim to empower healthcare professionals, and patients with actionable recommendations to optimize patient outcomes and enhance quality of life.”

Commenting on the guideline release **Michael J. Donovan, PhD, MD, Chief Medical Officer at Renalytix stated,** “Patients with type 2 diabetes and CKD are benefitting from the evidence gathered from a number of recent clinical trials and access to accurate risk assessment to inform care in a significant and growing healthcare challenge in the United States and globally. Renalytix welcomes these new updates from KDIGO which provide for clear and timely treatment strategies for health care professionals and we look forward to continuing to release evidence to highlight the role that KidneyIntelX is playing achieving the goal of optimizing patients’ outcomes and enhancing quality of life.”

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### About Chronic 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, more than 38 million people, currently have chronic kidney disease (CKD). Diabetes is the leading cause of kidney failure, accounting for 44% of new cases. Further, the CDC reports that 9 out of 10 adults with CKD do not know they have it and one out of two people with very low kidney function who are not on dialysis do not know they have CKD.<sup>1</sup> 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 in the United States die while waiting for a kidney transplant.

## About Type 2 Diabetes

More than 37 million Americans have diabetes (about 1 in 10), and approximately 90-95% of them have type 2 diabetes. Type 2 diabetes most often develops in people over age 45, but more and more children, teens, and young adults are also developing the disease<sup>2</sup>. Type 2 diabetes symptoms often develop over several years and approximately 23% of adults with type 2 diabetes are undiagnosed<sup>3</sup>. Type 2 diabetes affects many major organs, including the heart, blood vessels, nerves, eyes and kidneys. Diabetic kidney disease develops in 30-50% of type 2 diabetes patients<sup>4</sup>.

## About Renalytix

Renalytix (NASDAQ: RNLX) (LSE: RENX) is an in-vitro diagnostics and laboratory services company that is the global founder and leader in the new field of bioprognosis™ for kidney health. The leadership team, with a combined 200+ years of healthcare and in-vitro diagnostic experience, has designed its KidneyIntelX laboratory developed test to enable risk assessment for rapid progressive decline in kidney function in adult patients with T2D and early CKD (stages 1-3). We believe that by understanding how disease will progress, patients and providers can take action early to improve outcomes and reduce overall health system costs. For more information, visit [www.renalytix.com](http://www.renalytix.com).

## About the Kidney Disease: Improving Global Outcomes (KDIGO) 2024 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease (CKD)

The Kidney Disease: Improving Global Outcomes (KDIGO) 2024 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease (CKD) is an update to the KDIGO 2012 guideline on the topic. The aim is to assist clinicians caring for people with CKD, both adults and children. People receiving dialysis and kidney transplant recipients are not the focus of this guideline. The scope includes chapters dedicated to the evaluation of CKD, risk assessment in people with CKD, management to delay CKD progression and manage its complications, medical management and drug stewardship in CKD, and optimal models of CKD care. In addition, this guideline includes a comprehensive introduction from the guideline Co-Chairs, a patient foreword, a discussion of special population considerations, a presentation of the relative and absolute risks associated with specific outcomes from the CKD Prognosis Consortium (CKDPC), and an extensive section dedicated to research recommendations based on the current gaps in evidence. The goal of the guideline is to generate a useful resource for clinicians and patients by providing actionable recommendations based on a rigorous formal evidence review, practice points that serve to direct clinical care or activities for which a systematic review was not conducted, and useful infographics. The guideline targets a broad audience of healthcare providers involved in the care of people with CKD as well as people with CKD themselves while being mindful of implications for policy and payment. Development of this guideline update followed an explicit process of evidence review and appraisal. Treatment approaches and guideline recommendations are based on systematic reviews of relevant studies, and appraisal of the certainty of the evidence and the strength of recommendations followed the “Grading of Recommendations Assessment, Development, and Evaluation” (GRADE) approach. Limitations of the evidence are discussed, with areas of future research also presented.

## Sources

- 1 <https://www.theisn.org/blog/2020/11/27/more-than-850-million-worldwide-have-some-form-of-kidney-disease-help-raise-awareness/>
- 2 <https://www.cdc.gov/diabetes/basics/type2.html>
- 3 <https://www.cdc.gov/diabetes/data/statistics-report/index.html>
- 4 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5297507/>

## Forward Looking Statements

Statements contained in this announcement regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Examples of these forward-looking statements include statements concerning: the ability of KidneyIntelX to predict disease progression in people with CKD stages G1-G3 and guide early intervention; the ability of KidneyIntelX risk assessment to inform care resulting in sustained reduction in eGFR decline, improved diabetes management and improved cardiovascular health; and the ability of the KDIGO 2024 Clinical Guideline’s emphasis on multidisciplinary teamwork, patient engagement, and a holistic, evidence-based approach to care to help catalyze positive change, resulting in more coordinated CKD care management worldwide. Words such as “anticipates,” “believes,” “estimates,” “expects,” “intends,” “plans,” “seeks,” and similar expressions are intended to identify forward-looking statements. We may not actually achieve the plans and objectives disclosed in the forward-looking statements, and you should not place undue reliance on our forward-looking statements. Any forward-looking statements are based on management’s current views and assumptions and involve risks and uncertainties that could cause actual results, performance, or events to differ materially from those expressed or implied in such statements. These risks and uncertainties include, among others: that KidneyIntelX and kidneyintelX.dkd are based on novel artificial intelligence technologies that are rapidly evolving and potential acceptance, utility and clinical practice remains uncertain; we have only recently commercially launched KidneyIntelX; and risks relating to the impact on our business of the COVID-19 pandemic or similar public health crises. These and other risks are described more fully in our filings with the Securities and Exchange Commission (SEC), including our most recent Quarterly Report on Form 10-Q and the “Risk Factors” section of our Annual Report on Form 10-K filed with the SEC on September 28, 2023, and other filings we make with the SEC from time to time. All information in this press release is as of the date of the release, and we undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.