



renalytix™

# CAPABILITIES STATEMENT

**Renalytix, Inc.**  
1460 Broadway  
New York, NY 10036  
Phone: 646-397-3970 / 801-210-6751

**LAB ADDRESSES:**

**New York:**  
101 6th Avenue, 3rd FL  
New York, NY 10013

**Salt Lake City:**  
421 Wakara Way, Suite 309,  
Salt Lake City, UT 84108

**Business Size: Small**  
**DUNS:** 117063935  
**GSA CONTRACT NUMBER:** 36F79721D0148

**EXECUTIVE TEAM:**  
**James McCullough, Chief Executive Officer**  
jmccullough@renalytix.com

**Tom McLain, President**  
tmclain@renalytix.com

**O. James Sterling, Chief Financial Officer**  
ojsterling@renalytix.com

**CONTRACTING POINT OF CONTACT:**  
**Primary:** Shelley Glick, VP of Market Access  
Email: sglick@renalytix.com  
Phone: (512) 337-5559

**Secondary:** Jon Wisson, Sr. Manager Government Accounts  
Email: jwisson@renalytix.com  
Phone: (720) 635-6524

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[www.renalytix.com](http://www.renalytix.com)  
[www.kidneyintelx.com](http://www.kidneyintelx.com)

## About the Company

- Renalytix is the Global Founder & Leader in Kidney Disease Bioprognosis™.
- We innovated the world's first-of-kind solution to help doctors identify more accurately the 1 in 5 patients at greatest risk for kidney disease progression.
- KidneyIntelX™ is our breakthrough solution focused on kidney health, enabling integrated end-to-end care delivery to delay and prevent kidney disease progression.

## KidneyIntelX: Our bioprognostic™ solution

Initial Indication for adults with type 2 diabetes and early stage CKD (Stages 1,2,3)



Standard blood draw | no fasting  
(Biomarkers sTNFR1, sTNFR2, KIM-1)



Standard EHR elements  
eGFR, UACR, serum calcium, HbA1c,  
systolic BP, platelets, AST



Machine learning algorithm  
harmonizes data and generates a  
simple personalized risk assessment  
score.



Risk score + recommended  
actionable care pathways enable  
you to design a care plan that meets  
your patients' individual needs.



renalytix™

## Differentiators

We are committed to supporting clients with unparalleled quality and service:



Department of Health



Our diagnostic testing lab located in New York City is CLIA-certified and New York State DoH licensed. Our diagnostic testing lab located in Salt Lake City, Utah has a certificate of registration under CLIA and is currently able to provide testing services for patients in 47 states. The Utah laboratory is in the process of obtaining a CLIA-certificate of Compliance and state licenses to provide testing for patients in Pennsylvania, Maryland and New York in 2021.



National coverage of KidneyIntelX for 140 U.S. government departments, agencies and affiliates



Granted Breakthrough Device designation in 2019

De Novo 510(k) FDA clearance expected by end of 2021



Implementation of Medicare Coverage of Innovative Technology (MCIT) expected December 2021

Best of Breed Partnerships focusing on disrupting and transforming the course of Chronic Kidney Disease:



## Published Studies

- Clinical Utility of KidneyIntelX in Patients with Early Stages of Diabetic Kidney Disease in CANVAS Participants [https://www.kidneyintelx.com/wp-content/uploads/2021/04/WCN\\_CANVAS\\_Abstract\\_March\\_16\\_2021.pdf](https://www.kidneyintelx.com/wp-content/uploads/2021/04/WCN_CANVAS_Abstract_March_16_2021.pdf)
- Derivation and Validation of a Machine Learning Risk Score Using Biomarker and Electronic Patient Data to Predict Progression of Diabetic Kidney Disease [https://www.kidneyintelx.com/wp-content/uploads/2021/04/Chan2021\\_Article\\_DerivationAndValidationOfAMach.pdf](https://www.kidneyintelx.com/wp-content/uploads/2021/04/Chan2021_Article_DerivationAndValidationOfAMach.pdf)
- Clinical Utility of a New Prognostic Test to Predict the Risk of Kidney Function Decline in Diabetic Kidney Disease Patients [https://www.kidneyintelx.com/wp-content/uploads/2021/04/Decision-Impact-of-Kidney-Prognostic\\_NKF-2021\\_5-April-21.pdf](https://www.kidneyintelx.com/wp-content/uploads/2021/04/Decision-Impact-of-Kidney-Prognostic_NKF-2021_5-April-21.pdf)
- Evaluation of Payer Budget Impact Associated with the Use of Artificial Intelligence in vitro Diagnostic, KidneyIntelX™, to Modify DKD Progression <https://renalytixai.com/wp-content/uploads/2020/03/BHA-Renalytix-KidneyIntelX-NKF-Poster-3.25.20-FINAL-002.pdf>
- Initial Validation of a Machine Learning-derived Prognostic Test (Kidneyintelx) Integrating Biomarkers an Electronic Health Record Data to Predict Longitudinal Kidney Outcomes <https://kidney360.asnjournals.org/content/1/8/731>
- A qualitative study documenting unmet needs in the management of diabetic kidney disease (DKD) in the primary care setting <https://pubmed.ncbi.nlm.nih.gov/34001084/>

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