

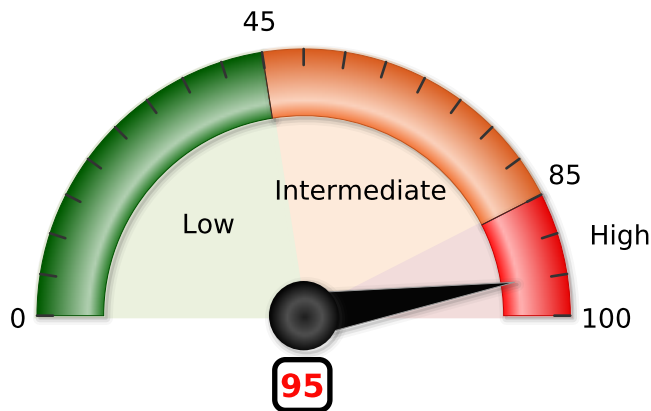
# Test Report

Ordered By	FRAN LAKE
Collection Date	03/07/2022
Received Date	03/08/2022
Specimen ID	665544

## PATIENT INFORMATION

NAME	SEX	DATE OF BIRTH	MEDICAL RECORD #
JANE LEE	F	01/01/1960	00998877

## RISK OF PROGRESSIVE DECLINE IN KIDNEY FUNCTION



# 95

Patients with a **high** KidneyIntelX score have an elevated risk of progressive decline in kidney function

The KidneyIntelX score ranges from 0-100 and correlates with the probability of progressive decline in kidney function in the study population. Risk classification is provided to guide interpretation of the risk score using cut-offs related to clinical outcomes.

SIGNED *Michael Donovan PhD, MD*

REPORT DATE 03/14/2022 TIME 10:05 AM (UTC)

Laboratory Director: Michael J. Donovan PhD, MD. Renalytix, 101 6th Avenue, 3rd Floor, Room 324, New York, NY 10013. CLIA Number: 3302156875

This test was developed and its performance characteristics determined by Renalytix, Inc. It has not been cleared or approved by the FDA nor is it currently required to be. The laboratory is regulated under CLIA as qualified to perform high-complexity testing. The test is used for clinical purposes. It should not be regarded as investigational or for research. See page 2 for further details.

## GUIDELINE RECOMMENDED CLINICAL PATHWAY

In addition to lifestyle modifications and metformin, the following pharmacologic strategies are recommended to reduce risks of CKD progression and cardiovascular disease

- Titrate ACEi or ARB to the maximum tolerated dose

**Strongly consider the following therapies:**

- SGLT2i (or GLP-1 RA if SGLT2i not tolerated or contraindicated)
- Non-steroidal MRA

### Frequency of Monitoring

- Monitor eGFR and UACR up to 3 times per year

- Specialist consultation, if clinically indicated

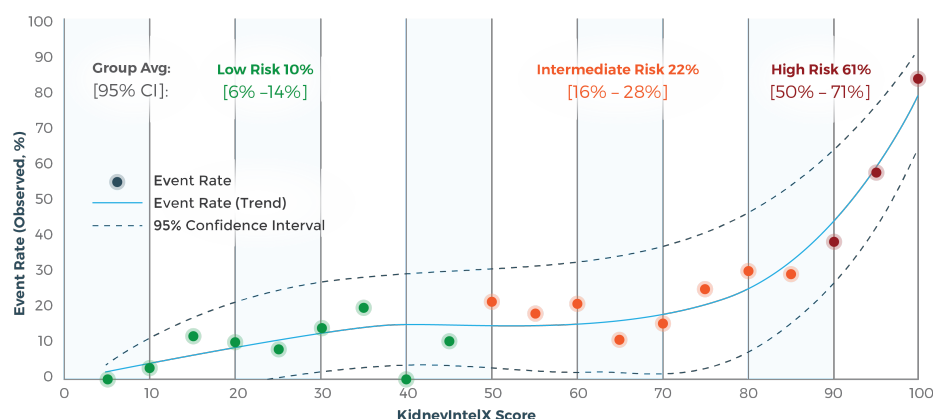
Clinical pathway recommendations based on the following guidelines:

- American Diabetes Association Standards of Medical Care in Diabetes 2022
- KDIGO 2020 Clinical Practice Guideline for Diabetes Management in CKD
- VA/DoD Clinical Practice Guidelines - Management of CKD (2019)
- KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of CKD

## CLINICAL VALIDATION STUDY RESULTS

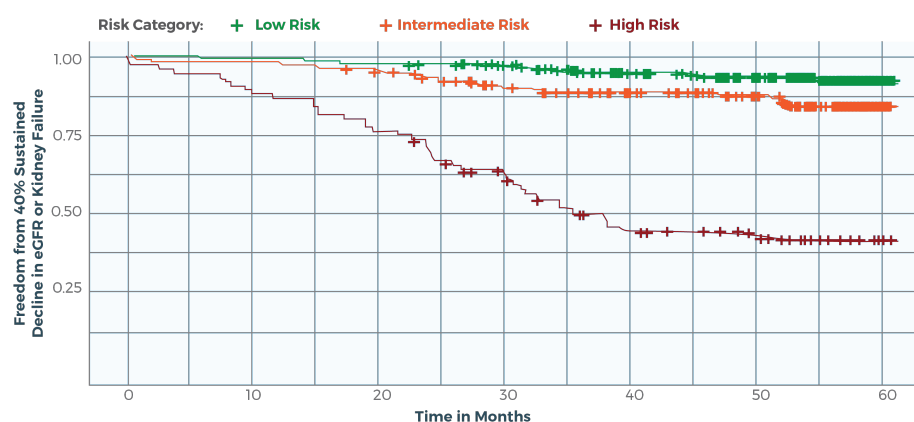
The KidneyIntelX test was validated in an analysis of patients with type 2 diabetes selected from two independent cohorts with chronic kidney disease (CKD) status representative of patients in the intended use population. The model relating KidneyIntelX score to progressive decline in kidney function over 5 years in the validation study is displayed in Figure 1a and 1b below.

**Figure 1a. KidneyIntelX Score and Event Rate of Progressive Decline in Kidney Function**



In the clinical validation study, patients who had a **KidneyIntelX score > 85 were classified as high risk**. The high risk group averaged a **61% probability of progressive decline in kidney function** up to 5 years compared to the low and intermediate risk groups that averaged a 10% and 22% probability, respectively.

**Figure 1b. Kaplan-Meier Curves by KidneyIntelX Risk Strata for the Endpoint of Sustained 40% Decline in eGFR or Kidney Failure**



**Patients classified as high risk by KidneyIntelX experienced faster progression to the endpoint of sustained 40% decline in eGFR or kidney failure.** Separation of the Kaplan-Meier curve in the high-risk group occurred within the first year and progressively declined over time.

Ref: Chan L, et al. MedRxiv 2020.06.01.20119522

## ABOUT THE TEST

KidneyIntelX is a quantitative electrochemiluminescence immunoassay using the MESO SECTOR S 600 instrument for measurement of soluble Tumor Necrosis Factor Receptor 1 (sTNFR1), soluble Tumor Necrosis Factor Receptor 2 (sTNFR2) and Kidney Injury Molecule-1 (KIM-1) in human plasma combined with clinical data, using an artificial intelligence-derived algorithm to produce a composite risk score.

It is indicated for use as an aid to further assess the risk of progressive decline in kidney function within a period of up to 5 years in patients over the age of 21 with Type 2 diabetes and existing chronic kidney disease. Patients with chronic kidney disease will have an estimated glomerular filtration rate [eGFR] of 30-59 ml/min/1.73 m<sup>2</sup> [G3a, G3b]\* or an eGFR ≥ 60 with albuminuria [UACR] ≥ 30 mg/g [A2, A3]\*.

A **progressive decline in kidney function** occurs when one or more of the following conditions are observed:

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

KidneyIntelX is not intended as a screening or stand-alone diagnostic test.

\* KDIGO 2012 Clinical Practice Guidelines for the Evaluation and Management of CKD