

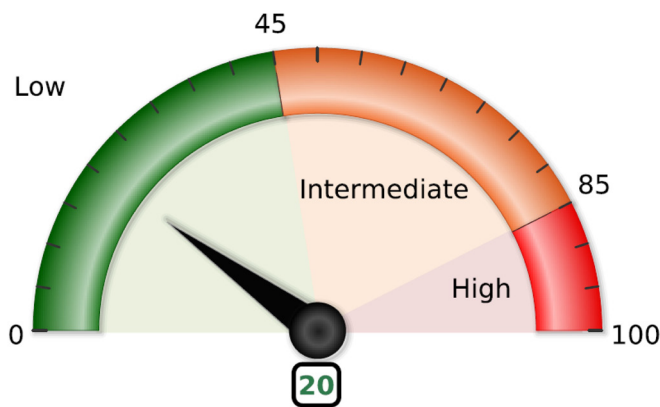
Test Report

Ordered by	Dr. Fran Lake
Collection Date	8/14/2020
Report Date	8/19/2020
Specimen ID	665544

PATIENT INFORMATION

NAME	SEX	DATE OF BIRTH	MEDICAL RECORD #
Jane Lee	F	1/1/1960	00998877

RISK OF PROGRESSIVE DECLINE IN KIDNEY FUNCTION



20

Patients with a **low** KidneyIntelX score have a low 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	DATE	TIME
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Laboratory Director: Michael J. Donovan PhD, MD, CLIA, Renalytix AI, 101 6th Ave, 3rd Floor, Room 324 New York, NY 10013 CLIA Number: 33D2156875

This test was developed and its performance characteristics determined by Renalytix AI, 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.

EXAMPLE OF CLINICAL PATHWAY WITH KIDNEYINTELX

Frequency of Monitoring ¹	Strategy to Reduce Diabetic Kidney Disease Progression and Cardiovascular Disease ^{2,3}
Monitoring 1x/year	Maintain current level of treatment with ACEi/ARB, antihypertensives, and anti-hyperglycemic agents unless BP or glucose are uncontrolled

¹ KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease https://kdigo.org/wp-content/uploads/2017/02/KDIGO_2012_CKD_GL.pdf

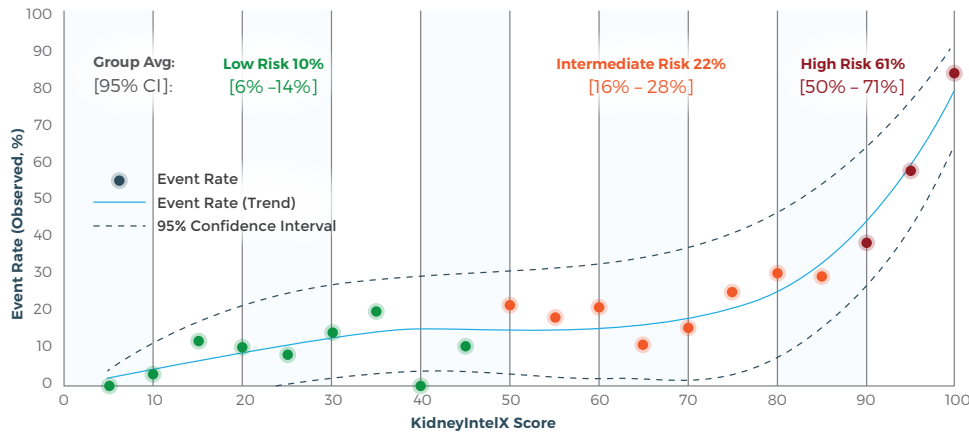
² Executive Summary of the 2020 KDIGO Diabetes Management in CKD Guideline. <https://doi.org/10.1016/j.kint.2020.06.024>

³ ADA guidelines. https://care.diabetesjournals.org/content/43/Supplement_1/S135

CLINICAL VALIDATION STUDY RESULTS

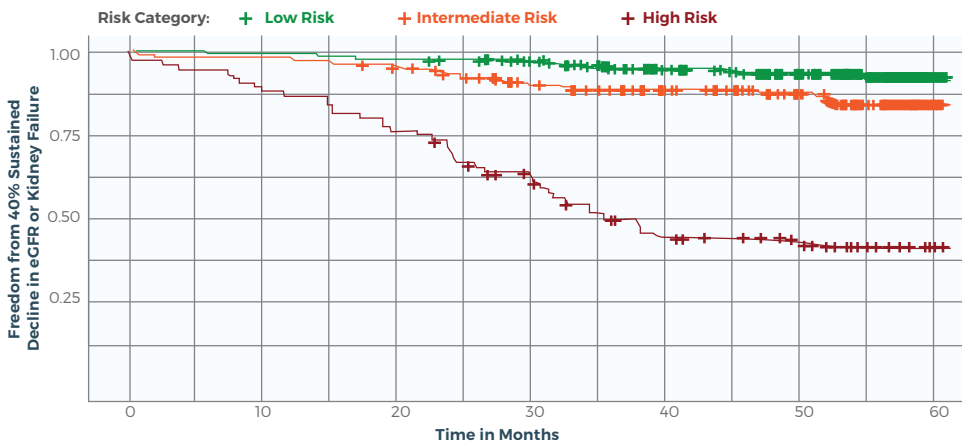
The KidneyIntelX test was validated in an analysis of 1146 patients with type 2 diabetes selected from two independent cohorts with chronic kidney disease status representative of patients in the intended use population. The model relating the KidneyIntelX score to progressive decline in kidney function up to 5 years in the validation study is displayed in Figures 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 ≤45** were classified as **low risk**. The **low risk patient group averaged a 10% probability** of progressive decline in kidney function up to 5 years compared to the intermediate- and high risk groups that averaged a 22 and 61% 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 stratum 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 m² [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 m²/year
- Sustained decrease in eGFR ≥ 40%; confirmed at least 3 months apart
- Kidney Failure, defined by sustained eGFR < 15 ml/min/1.73 m², initiation of long-term dialysis, or kidney transplantation.

*KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease
KidneyIntelX is not intended as a screening or stand-alone diagnostic test.