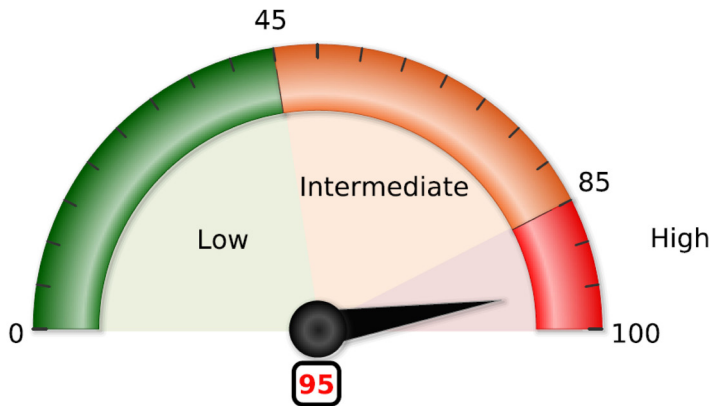


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|-----------------|---------------|
| Ordered by      | Dr. Fran Lake |
| Collection Date | 8/14/2020     |
| Report Date     | 8/19/2020     |
| Specimen ID     | 665544        |

### PATIENT INFORMATION

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

### RISK OF PROGRESSIVE DECLINE IN KIDNEY FUNCTION



# 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 | DATE | TIME |
|--------|------|------|
|--------|------|------|

Laboratory Director: Michael J. Donovan PhD, MD, CLIA, Renalytix AI, 101 6th Ave, 3rd Floor, Room 324 New York, NY 10013 CLIA Number: 33D2156875

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### EXAMPLE OF CLINICAL PATHWAY WITH KIDNEYINTELX

| Frequency of Monitoring / Referral <sup>1</sup> |                        | Comprehensive Strategy to Maximize Protection for Diabetic Kidney Disease Progression and Cardiovascular Disease <sup>2,3</sup> |   |
|---|------------------------|---|---|
| Monitoring<br>3x/year                           | Nephrology<br>Referral | Titrate ACEi or ARB to<br>maximally tolerated dose  | Strongly consider SGLT2 inhibitor<br>therapy unless contraindicated |

<sup>1</sup> 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](https://kdigo.org/wp-content/uploads/2017/02/KDIGO_2012_CKD_GL.pdf)

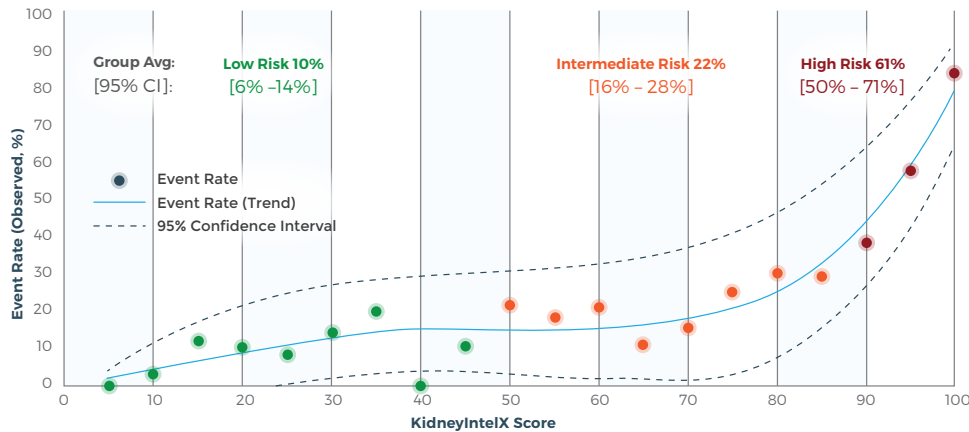
<sup>2</sup> Executive Summary of the 2020 KDIGO Diabetes Management in CKD Guideline. <https://doi.org/10.1016/j.kint.2020.06.024>

<sup>3</sup> ADA guidelines. [https://care.diabetesjournals.org/content/43/Supplement\\_1/S135](https://care.diabetesjournals.org/content/43/Supplement_1/S135)

## CLINICAL VALIDATION STUDY RESULTS

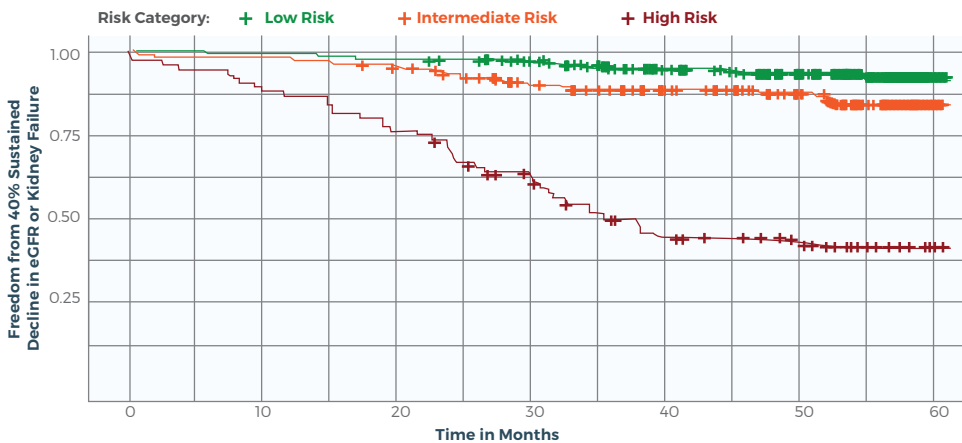
The KidneyIntelX test was validated in an analysis of 1146 patients with type 2 diabetes selected from two independent cohorts with chronic kidney disease status representative of patients in the intended use population. The model relating the KidneyIntelX score to progressive decline in kidney function 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 > 85** were classified as **high risk**. The high risk patient 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 end point 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 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.

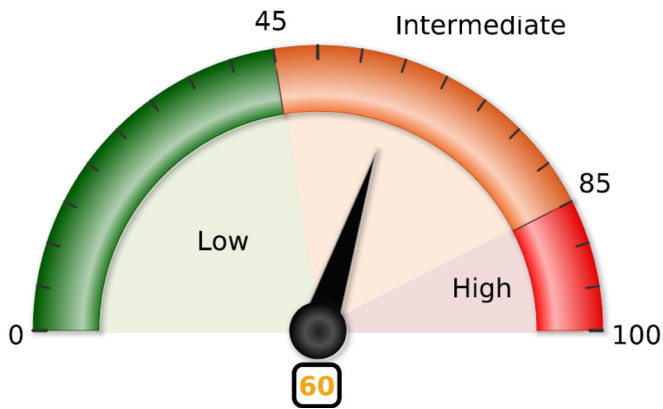
\*KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease  
KidneyIntelX is not intended as a screening or stand-alone diagnostic test.

|                 |               |
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### PATIENT INFORMATION

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

### RISK OF PROGRESSIVE DECLINE IN KIDNEY FUNCTION



# 60

Patients with a an **intermediate** KidneyIntelX score have an intermediate 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

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### EXAMPLE OF CLINICAL PATHWAY WITH KIDNEYINTELX

| Frequency of Monitoring <sup>1</sup> | Strategy to Reduce Diabetic Kidney Disease Progression and Cardiovascular Disease <sup>2,3</sup> |   |
|--------------------------------------|--|---|
| Monitoring<br>2x/year                | Treat with ACEi or ARB and antihypertensives   | Consider SGLT2 Inhibitors if clinically indicated |

<sup>1</sup> 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](https://kdigo.org/wp-content/uploads/2017/02/KDIGO_2012_CKD_GL.pdf)

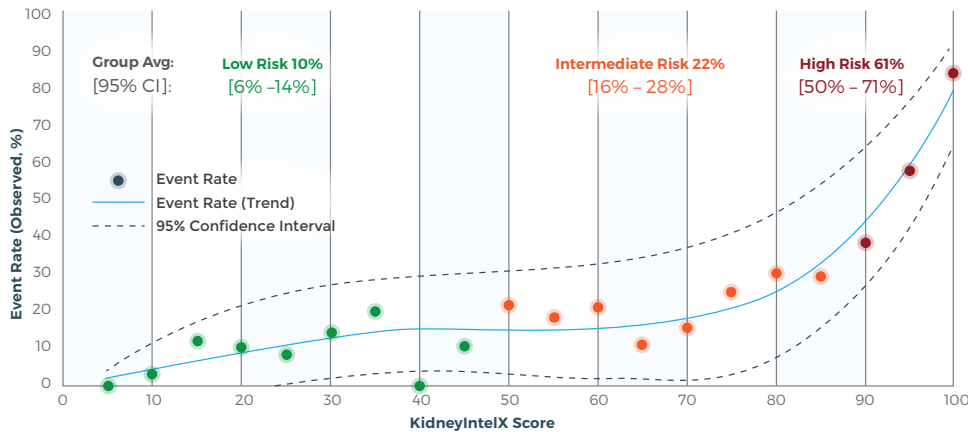
<sup>2</sup> Executive Summary of the 2020 KDIGO Diabetes Management in CKD Guideline. <https://doi.org/10.1016/j.kint.2020.06.024>

<sup>3</sup> ADA guidelines. [https://care.diabetesjournals.org/content/43/Supplement\\_1/S135](https://care.diabetesjournals.org/content/43/Supplement_1/S135)

## CLINICAL VALIDATION STUDY RESULTS

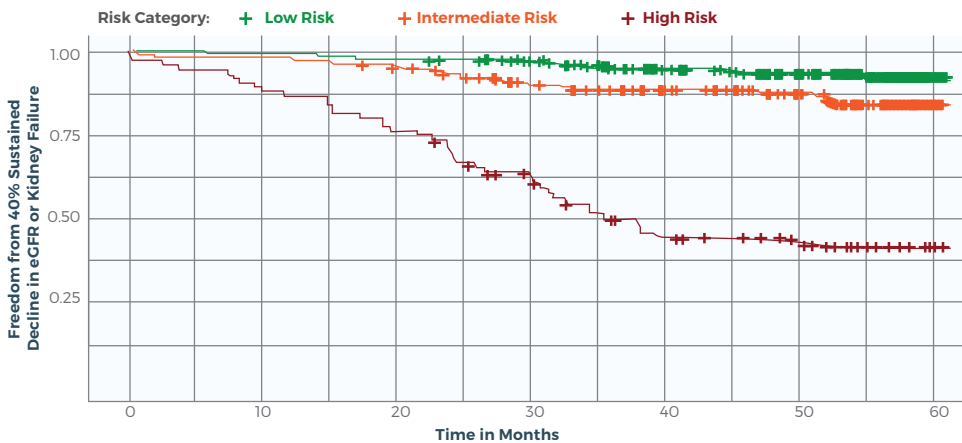
The KidneyIntelX test was validated in an analysis of 1146 patients with type 2 diabetes selected from two independent cohorts with chronic kidney disease status representative of patients in the intended use population. The model relating the KidneyIntelX score to progressive decline in kidney function 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  $\geq 50$  and  $\leq 85$  were classified as intermediate risk. The intermediate risk patient group averaged a **22% probability** of progressive decline in kidney function up to 5 years compared to low-and high risk groups that averaged a 10 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 end point 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

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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  $\geq 60$  with albuminuria [UACR]  $\geq 30$  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  $\geq 5$  ml/min/1.73 m<sup>2</sup>/year
- Sustained decrease in eGFR  $\geq 40\%$ ; 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.

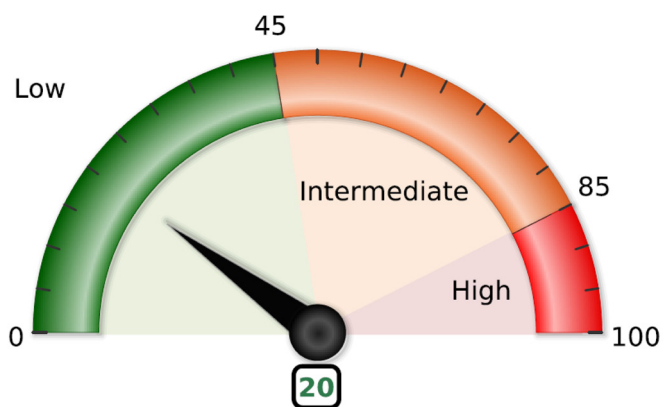
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|----------|-----|---------------|------------------|
| Jane Lee | F   | 1/1/1960      | 00998877         |

### 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**

Laboratory Director: Michael J. Donovan PhD, MD, CLIA, Renalytix AI, 101 6th Ave, 3rd Floor, Room 324 New York, NY 10013 CLIA Number: 33D2156875

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### EXAMPLE OF CLINICAL PATHWAY WITH KIDNEYINTELX

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

<sup>1</sup> 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](https://kdigo.org/wp-content/uploads/2017/02/KDIGO_2012_CKD_GL.pdf)

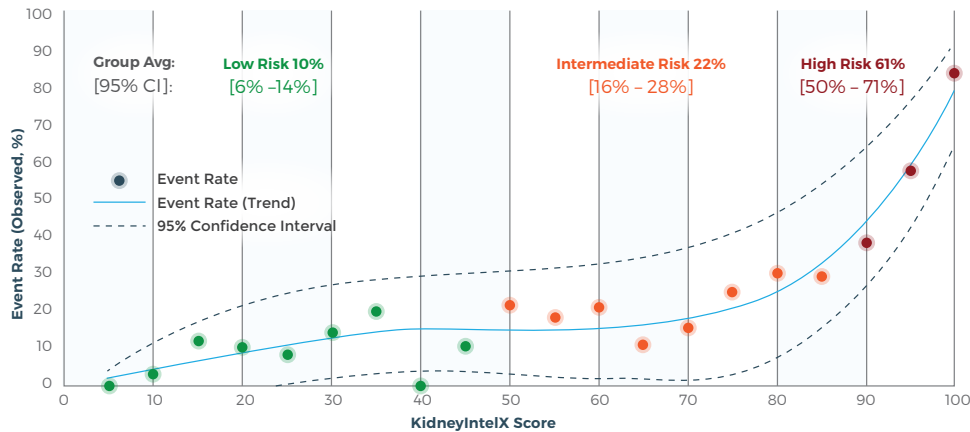
<sup>2</sup> Executive Summary of the 2020 KDIGO Diabetes Management in CKD Guideline. <https://doi.org/10.1016/j.kint.2020.06.024>

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## CLINICAL VALIDATION STUDY RESULTS

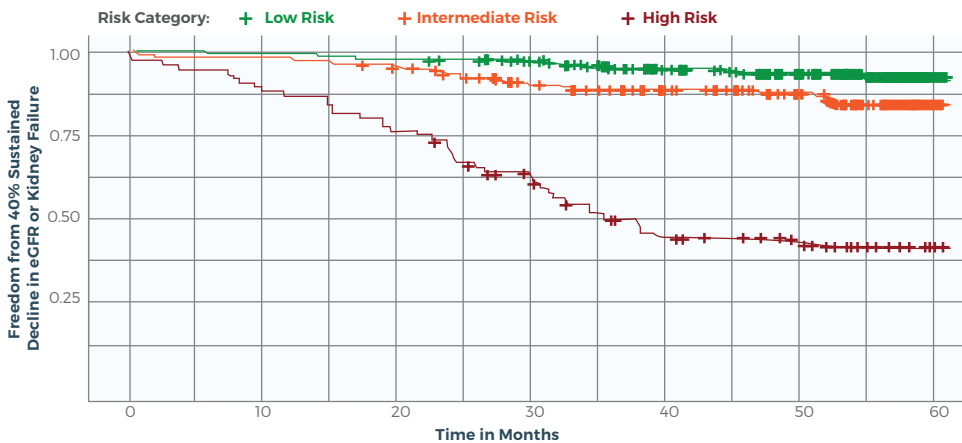
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**Figure 1a. KidneyIntelX Score and Event Rate of Progressive Decline in Kidney Function**



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

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- Kidney Failure, defined by sustained eGFR < 15 ml/min/1.73 m<sup>2</sup>, initiation of long-term dialysis, or kidney transplantation.

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