kidneyintelX.dkd™

Product and Test Name	Current Version	Materials Provided	Specimen Type	Sample Volume
kidneyintelX.dkd	1	kidneyintelX.dkd Specimen Collection Kit Test Requisition Form	Whole Blood	≥ 4 ml

Intended Use

The kidneyintelX.dkd is for in-vitro diagnostic use for the determination of a kidneyintelX.dkd Level using an algorithm to combine clinical variables (blood urea nitrogen (BUN), hemoglobin A1c (HbA1c) and urine albumin creatinine ratio (UACR)) and the quantitative measurements of tumor necrosis factor receptor-1 (TNFR-1), tumor necrosis factor receptor-2 (TNFR-2) and kidney injury molecule-1 (KIM-1) in human plasma employing a Meso Sector S 600 electrochemiluminescence immunoassay. It is indicated for use as an aid in assessment of the risk of progressive decline in kidney function (sustained decrease in eGFR greater than or equal to 40% lasting more than 3 months) within a period of up to 5 years following kidneyintelX.dkd Level measurement in adult patients with type 2 diabetes and existing chronic kidney disease (defined for the purposes of this device as patients with an estimated glomerular filtration rate of 30-59 ml/min/1.73 m² or eGFR ≥ 60 ml/min/1.73 m² with albuminuria (UACR ≥ 30 mg/g)).

kidneyintelX.dkd is not intended for screening or as a stand-alone diagnostic test.

Summary and Explanation

Chronic kidney disease (CKD) is a major cause of morbidity and mortality throughout the world, affecting nearly 850 million individuals, including over 38 million in the United States.[1] The leading cause of CKD in the United States is type 2 diabetes and approximately 40% of individuals have CKD, known as diabetic kidney disease (DKD).[1,2] DKD is defined by the presence of elevated urinary albumin excretion (albumin to creatinine ratio ≥ 30 mg/g) or low estimated glomerular filtration rate (eGFR < 60 ml/min/1.73 m²) in a person with type 2 diabetes.

If left untreated, DKD can progress to end stage kidney disease (ESKD), which is defined as a sustained eGFR of <15 ml/min/1.73 m² and often requires life-long maintenance dialysis or a kidney transplant.[3]

The clinical course of DKD is highly variable and includes fluctuating levels of albuminuria and a progressive loss of kidney function represented first as a compensatory increase and then gradual lowering in eGFR.[5,5] This disease process, without therapeutic intervention, will inevitably lead to ESKD, cardiovascular disease, and death.[6]

Several blood-based biomarkers reflecting the underlying disease pathophysiology in DKD have been associated with the risk of a progressive decline in kidney function.[7] Plasma tumor necrosis factors receptors TNFR-1 and

TNFR-2 have been identified at the cellular level in kidney endothelial cells, podocytes, and renal tubular epithelial cells. TNFR-1 and TNFR-2 have been shown to be responsible for the upregulation of proapoptotic signals and are important mediators of glomerulonephritis.[8,9,10,11,12] Kidney injury molecule-1 (KIM-1) expression is upregulated in cases of ischemia, hypoxia, and cellular tubular injury; and it has been implicated in biologic mechanisms of CKD in the setting of diabetes mellitus (e.g., activation of phagocytic cells, autophagy, and immune cellular activation).[13,14,15,16]

The kidneyintelX.dkd test combines measurements of plasma TNFR-1, TNFR-2, KIM-1, with clinical features (UACR, HbA1c, BUN) and applies an algorithm to report progressive decline in kidney function, as measured by a sustained decrease in eGFR.

The kidneyintelX.dkd is for prognostic use in patients with early-stage DKD, in conjunction with other laboratory findings and clinical assessments, to assess the progressive decline in kidney function. The kidneyintelX.dkd test, therefore, may be useful in determining which patients could benefit from additional examinations, increased monitoring, potential lifestyle changes, and treatment interventions.

Description of Test

The kidneyintelX.dkd test is comprised of the following:

A | A multiplex electrochemiluminescence assay for the in vitro quantitative determination of tumor necrosis factor receptors 1 and 2 (TNFR-1, TNFR-2), and kidney injury molecule 1 (KIM-1) in human plasma (whole blood K_2EDTA blood collection tube). The assay is designed for use with the MESO SECTOR® S 600 instrument to quantify the three biomarkers. The assay is performed by trained laboratory personnel at Renalytix using the assay components that includes the kidneyintelX.dkd 96-well plate, the detection antibody, calibrator, and controls along with the MesoScale Diagnostics diluents, blocker, wash buffer and read buffer.

B | The kidneyintelX.dkd Portal, a cloud-based system that contains the software algorithm, provides a kidneyintelX.dkd Level (High, Moderate, Low) by combining the biomarker results from the assay and patient-specific results for UACR, HbA1c, and BUN. The patient specific clinical data needed for kidneyintelX.dkd level determination is listed in the kidneyintelX.dkd Test Requisition Form.

C | A kidneyintelX.dkd Test Report containing the kidneyintelX.dkd level and interpretation of the test result is provided to the ordering physician.

The kidneyintelX.dkd test is an in-vitro diagnostic performed by a Renalytix laboratory and is for Prescription Use Only.

Measurement Intervals

KIM-1	12 pg/mL – 3915 pg/mL The kidneyintelX.dkd Levels are not reported for subjects with KIM-1 values outside of the measuring interval.
TNFR-1	1057 pg/mL to 14,322 pg/mL The kidneyintelX.dkd Levels are not reported for subjects with TNFR-1 values outside of the measuring interval.
TNFR-2	4270 pg/mL to 43,291 pg/mL The kidneyintelX.dkd Levels are not reported for subjects with TNFR-2 values outside of the measuring interval.
UACR	1 mg/g - 6022 mg/g The kidneyintelX.dkd Levels are not reported for subjects with UACR values outside of the measuring interval. UACR values must be provided from quantitative devices.
HbA1c	4.9% to 15.6% The kidneyintelX.dkd Levels are not reported for subjects with HbA1c values outside of the measuring interval.
BUN	6 mg/dL to 60 mg/dL The kidneyintelX.dkd Levels are not reported for subjects with BUN values outside of the measuring interval.

Warnings and Precautions

For Prescription Use Only.

Warning!	Enbrel® interferes with the ability to accurately measure TNFR-2 in patient specimens and is contra-indicated for patients when ordering kidneyintelX.dkd testing.
Warning!	Hemolyzed samples will not be analyzed. The kidneyintelX.dkd test result will not be generated.

Specimen Collection and Handling

Whole blood is collected in K_2EDTA tubes.

Follow the kidneyintelX.dkd Specimen Collection Kit Instructions For Use for specimen collection, storage and transportation.

Interpretation of Results

The kidneyintelX.dkd test reports one of three Levels (Low, Moderate and High) associated with progressive decline in kidney function.

Interpretation of results should be performed according to the data in the *'Clinical Performance'* section and in conjunction with the patient's medical history, clinical presentation, and other findings.

Expected Values

Expected values for apparently healthy subjects and for patients with type 2 diabetes but without CKD were established in accordance with CLSI guideline EP28-A3c[17]. Study subjects were selected to be representative of the U.S. population. The absence of chronic kidney disease (CKD) was defined as those subjects with eGFR ≥ 60 mL/min/1.73 m^2 (G1, G2), and UACR < 30 mg/g (A1), categorized as normal or mildly increased albuminuria, or low risk (if no other markers of kidney disease, no CKD). The proportion of patients in each kidneyintelX.dkd Level was established for this population for reference purposes only. The kidneyintelX.dkd test is not intended for subjects with diabetes without CKD.

Population	Gender	Race/Ethnicity	N	Age Range	kidneyintelX.dkd Level
Apparently Healthy	Female (64%) Male (36%)	African American (12%) Caucasian (45%) Other (43%)	121	18 to 58	Low (100%) Moderate (0%) High (0%)
Patients with Type 2 Diabetes without CKD	Female (64%) Male (36%)	African American (30%) Caucasian (8%) Other (62%)	104	29 to 80	Low (77%) Moderate (22%) High (1%)

Limitations

- The kidneyintelX.dkd test is for In-Vitro Diagnostic Use: Only performed at a Renalytix clinical laboratory.
- The kidneyintelX.dkd test is not intended as a screening or stand-alone diagnostic test.
- The kidneyintelX.dkd test is not for use in the diagnosing or staging of diabetic kidney disease.
- The kidneyintelX.dkd test results are intended to be used in conjunction with other clinical and diagnostic findings, consistent with professional standards of practice, including information obtained by alternative methods, and clinical evaluation, and physician assessment as appropriate.
- Always interpret kidneyintelX.dkd test results in conjunction with the patient's medical history, clinical presentation, physician assessment, and other findings.
- A kidneyintelX.dkd Low Level is associated with a lower prognostic risk, but disease progression will occur in some patients with a kidneyintelX.dkd Low Level test result.
- A kidneyintelX.dkd High Level is associated with a higher prognostic risk, but disease progression does not occur in some patients with a kidneyintelX.dkd High Level test result.
- Only K_2EDTA plasma samples can be analyzed for the measurement of KIM-1, TNFR-1, and TNFR-2 used to generate the kidneyintelX.dkd test results.
- Only measurements of UACR, HbA1c, and BUN within measuring intervals and eGFR and serum creatinine detailed in the Test Requisition Form taken within 12 months prior to sample collection should be used with the kidneyintelX.dkd test.
- All inputs to the kidneyintelX.dkd algorithm are subject to measurement and intra-individual variability resulting in some subjects being reported at different kidneyintelX.dkd Levels on repeat testing.

Performance Characteristics

Clinical Performance

The prognostic performance of kidneyintelX.dkd was assessed in 657 adult subjects with type 2 diabetes and existing chronic kidney disease enrolled into the Bio*Me* Biobank of the Mount Sinai Health System in New York between 2008 and 2019. All participants selected for the analyses satisfied the kidneyintelX.dkd intended use.

The baseline characteristics of the clinical study population included in the analysis are described in Table 1.

Table 1. Clinical Study Population – Baseline Characteristics

	Total N=657
Age	
Median (IQR)	72 (64, 78)
Min, Max	38, 90
Sex – n (%)	
Male	284 (43.2)
Female	373 (56.8)
Race – n (%)	
American Indian / Alaska Native	3 (0.5)
Asian	27 (4.1)
Black / African American	240 (36.5)
Native Hawaiian / Pacific Islander	0 (0)
White	100 (15.2)
Other	284 (43.2)
No Response	3 (0.5)
Ethnicity – n (%)	
Hispanic	264 (40.2)
Non-Hispanic	393 (59.8)
Baseline eGFR (ml/min/1.73 m^2)	
Median (IQR)	57.0 (46.8 - 79.8)
eGFR: 30 to 59 ml/min/1.73 m^2	59%
eGFR ≥ 60 ml/min/1.73 m^2 with UACR ≥ 30 mg/g	41%
Baseline UACR (mg/g)	
Median (IQR)	52.0 (20 – 214)
Clinical History – n (%)	
Hypertension	568 (86.5)
Heart Failure	78 (11.9)
CAD	138 (21.0)

IQR: Interquartile range | CAD: Coronary artery disease | Race: Self-identified by subjects

An analysis of the study population estimated the prognostic ability of the kidneyintelX.dkd test at baseline to predict the risk of progressive decline in kidney function up to 5 years following enrollment (median: 1385 days / IQR: (757,1705) days).

Progressive decline in kidney function is defined as a sustained decrease in eGFR ≥ 40% within a period of up to 5 years following kidneyintelX.dkd measurement. For study analysis, sustained decrease was confirmed with a second eGFR value showing > 40% decline at least 3 months after the index value.

Progressive decline in kidney function was assessed according to observed risk proportion at each kidneyintelX.dkd Level as shown in Table 2.

Table 2. Risk of Progressive Decline in Kidney Function Decline

kidneyintelX.dkd Level	Number of Subjects	Number of Subjects with Progressive Decline in Kidney Function	Percent of Patients Experiencing Progressive Decline in Kidney Function (95% CI)[a]
Low	374	17	4.6% (2.7% – 7.2%)
Moderate	228	38	16.7% (12.1% – 22.2%)
High	55	23	41.8% (28.7% – 55.9%)

[a] Exact Binomial confidence interval.

An additional analysis of the study population estimated the prognostic ability of the kidneyintelX.dkd test at baseline to predict ESKD up to 5 years following enrollment (median: 1385 days / IQR: (757,1705) days). ESKD is defined as sustained eGFR < 15 ml/min/1.73 m^2 within a period of up to 5 years following kidneyintelX.dkd measurement.

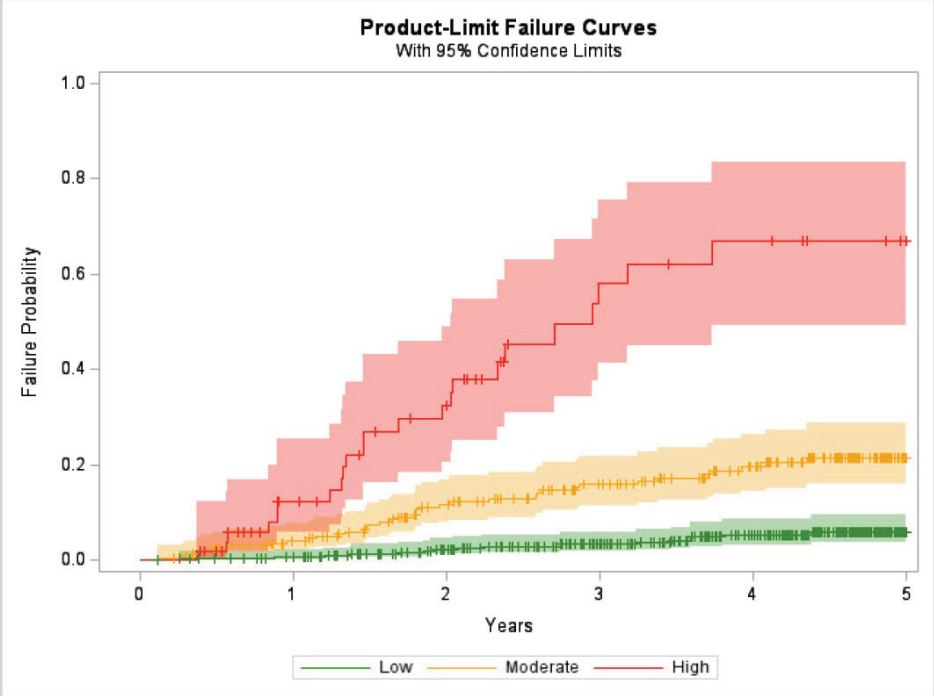
Progression to ESKD was assessed according to observed risk proportion at each kidneyintelX.dkd Level as shown in Table 3.

Table 3. Risk of End Stage Kidney Disease

kidneyintelX.dkd Level	Number of Subjects	Number of Subjects with End Stage Kidney Disease	Percent of Patients Experiencing End Stage Kidney Disease (95% CI)[a]
Low	374	0	0.0%
Moderate	228	7	3.1% (1.2% – 6.2%)
High	55	10	18.2% (9.1% – 30.9%)

[a] Exact Binomial confidence interval.

Kaplan-Meier curves were plotted for each of the kidneyintelX.dkd Levels to display the fraction of subjects with progressive decline in kidney function over time up to a maximum follow-up of 5 years. Progressive decline in kidney function was assessed according to estimated cumulative risk at each kidneyintelX.dkd Level as shown in Figure 1. Cox Proportional Hazard Ratios are also presented in Figure 1.



Numbers at Risk

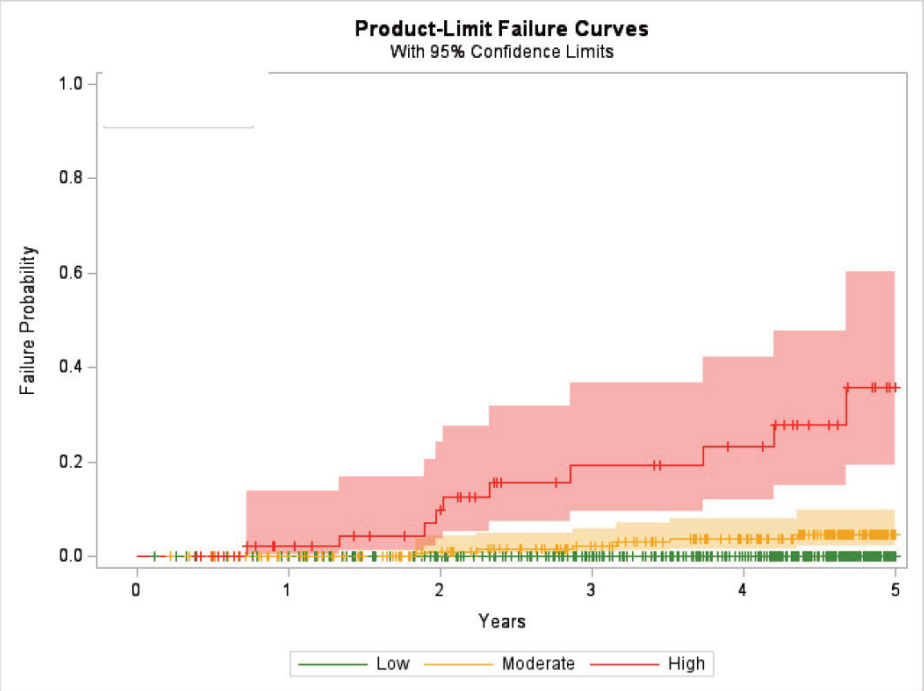
KidneyIntelX.dkd Level	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
Low	374	360	318	270	205	17
Moderate	228	202	161	129	98	8
High	55	38	25	10	7	2

KidneyIntelX.dkd Level	Number of Subjects	Estimated Rate at 5 Years [a] (95% CI)	Unadjusted Cox Proportional Hazard Ratios (95% CI)	Adjusted Cox Proportional Hazard Ratios [b] (95% CI)
Low	374	5.9% (3.6% – 9.4%)	1.00	1.00
Moderate	228	21.5% (15.9% - 28.6%)	4.29 (2.42 – 7.61)	3.83 (2.10 – 6.99)
High	55	66.9% (49.3% - 83.5%)	18.29 (9.68 – 34.55)	7.81 (3.08 – 19.81)

[a] Failure estimates and corresponding confidence interval from Kaplan-Meier analysis.
[b] KidneyIntelX.dkd Levels were adjusted for a model comprising of clinical and demographic features associated with kidney disease progression (UACR, eGFR, HbA1c, systolic blood pressure, age, race, and gender).

Figure 1. Kaplan-Meier curves and Cox Proportional Hazard Ratios for progressive decline in kidney function over time up to a maximum follow-up of 5 years.

Additionally, Kaplan-Meier curves were plotted for each of the kidneyintelX.dkd Levels to display the fraction of subjects with ESKD over time up to a maximum follow-up of 5 years. ESKD was assessed according to estimated cumulative risk at each kidneyintelX.dkd Level as shown in Figure 2. Cox Proportional Hazard Ratios are also presented in Figure 2.



Numbers at Risk

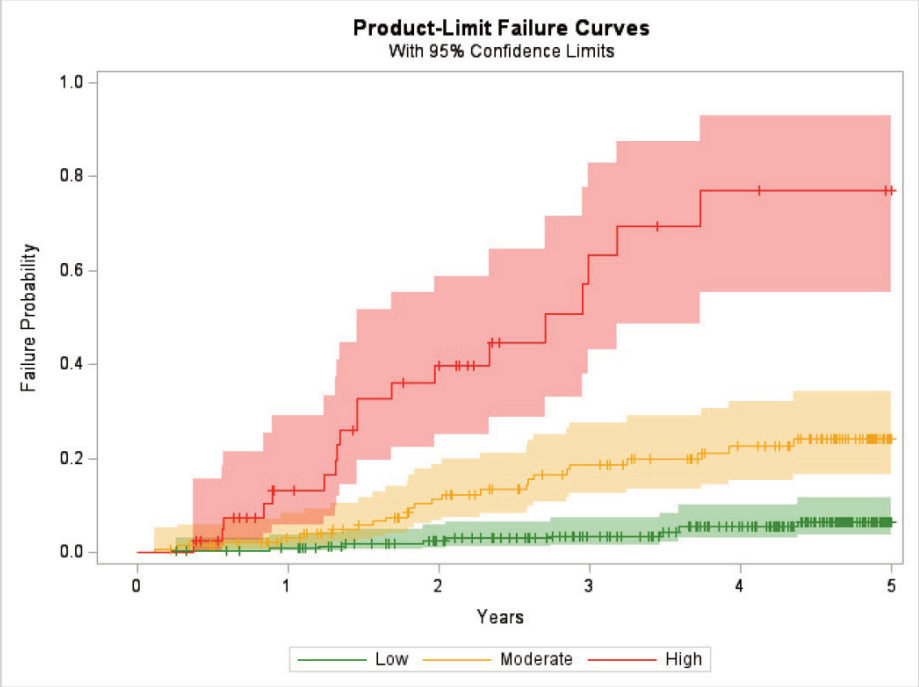
KidneyIntelX.dkd Level	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
Low	374	362	326	281	217	20
Moderate	228	211	181	150	120	11
High	55	43	34	22	18	2

KidneyIntelX.dkd Level	Number of Subjects	Estimated Rate at 5 Years [a] (95% CI)	Unadjusted Cox Proportional Hazard Ratios [b] (95% CI)	Adjusted Cox Proportional Hazard Ratios [b] (95% CI)
Low	374	0% (0.0% - 0.0%)	N/A [c]	N/A [c]
Moderate	228	4.7% (2.2% - 9.7%)	1.00	1.00
High	55	35.9% (19.3% - 60.1%)	8.51 (3.23 – 22.41)	5.25 (1.19 – 23.27)

[a] Failure estimates and corresponding confidence interval from Kaplan-Meier analysis.
[b] KidneyIntelX.dkd Levels were adjusted for a model comprising of clinical and demographic features associated with kidney disease progression (UACR, eGFR, HbA1c, systolic blood pressure, age, race, and gender).
[c] There were no events in KidneyIntelX.dkd Level Low, and therefore the Hazard Ratios cannot be computed.

Figure 2. Kaplan-Meier curves and Cox Proportional Hazard Ratios for ESKD over time up to a maximum follow-up of 5 years.

Kaplan-Meier curves were plotted to show performance of kidneyintelX.dkd in sub-populations represented in the clinical performance study as defined by eGFR (Figures 3 and 4) and race (Figures 5 and 6)[18].



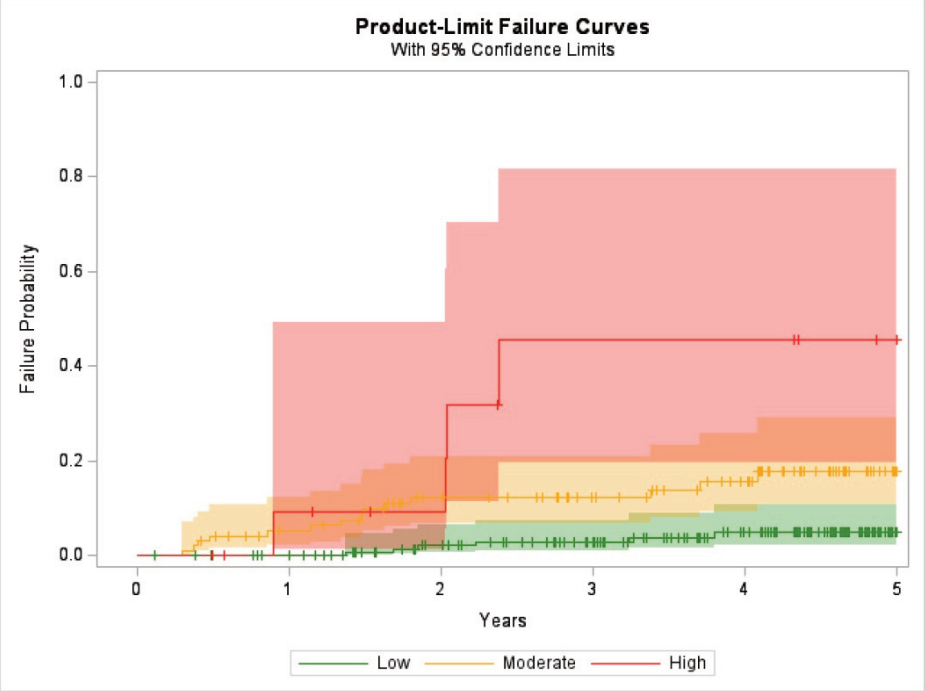
Numbers at Risk

KidneyIntelX.dkd Level	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
Low	215	208	186	157	124	7
Moderate	131	117	92	74	56	5
High	42	28	17	6	3	1

KidneyIntelX.dkd Level	Number of Subjects	Percent of Patients Experiencing Progressive Decline in Kidney Function (95% CI) [a]	Estimated Rate at 5 Years [b] (95% CI)
Low	215	5.1% (2.6% - 9.0%)	6.5% (3.6% – 11.7%)
Moderate	131	18.3% (12.1% - 26.0%)	24.2% (16.7% - 34.2%)
High	42	45.2% (29.9% - 61.3%)	77.0% (55.4% - 93.1%)

[a] Exact Binomial confidence interval.
[b] Failure estimates and corresponding confidence interval from Kaplan-Meier analysis.

Figure 3. Kaplan-Meier curve for progressive decline in kidney function over time up to a maximum follow-up of 5 years of individuals with eGFR 30 – 59 mL/min/1.73 m^2.



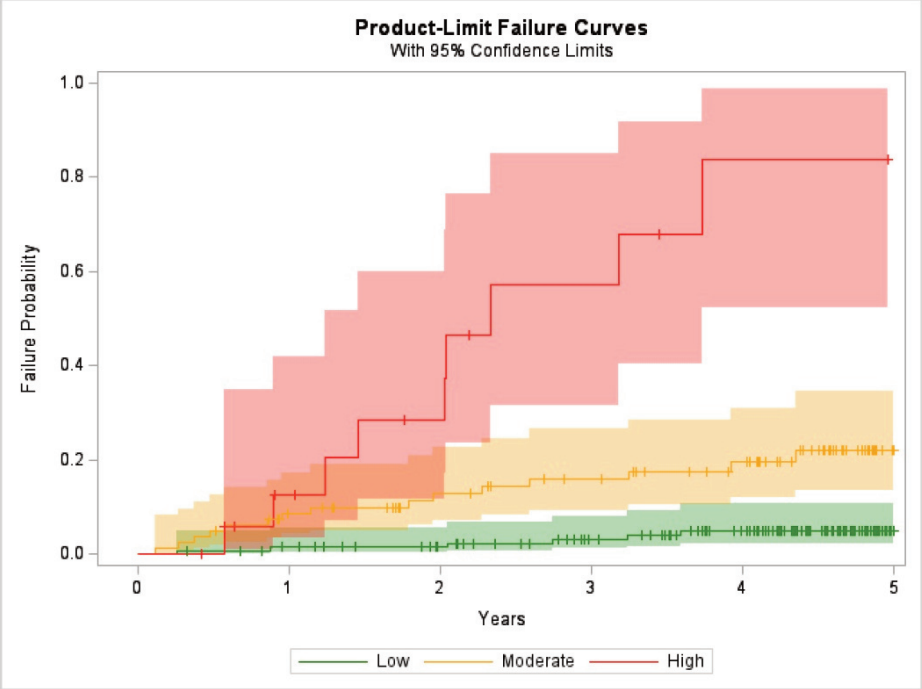
Numbers at Risk

KidneyIntelX.dkd Level	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
Low	159	152	132	113	81	10
Moderate	97	85	69	55	42	3
High	13	10	8	4	4	1

KidneyIntelX.dkd Level	Number of Subjects	Percent of Patients Experiencing Progressive Decline in Kidney Function (95% CI) [a]	Estimated Rate at 5 Years [b] (95% CI)
Low	159	3.8% (1.4% - 8.0%)	4.9% (2.2% - 10.8%)
Moderate	97	14.4% (8.1% - 23.0%)	17.9% (10.7% - 29.0%)
High	13	30.8% (9.1% - 61.4%)	45.5% (19.5% - 81.6%)

[a] Exact Binomial confidence interval.
[b] Failure estimates and corresponding confidence interval from Kaplan-Meier analysis.

Figure 4. Kaplan-Meier curve for progressive decline in kidney function over time up to a maximum follow-up of 5 years of individuals with eGFR ≥ 60 mL/min/1.73 m^2.



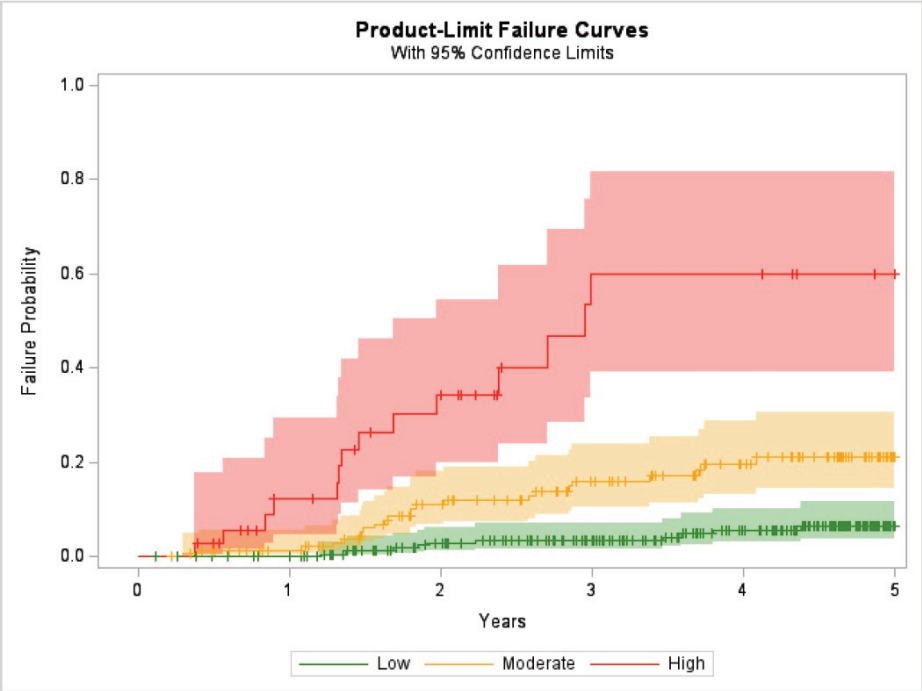
Numbers at Risk

KidneyIntelX.dkd Level	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
Low	140	134	125	110	90	8
Moderate	82	70	59	52	43	3
High	18	12	8	4	1	0

KidneyIntelX.dkd Level	Number of Subjects	Percent of Patients Experiencing Progressive Decline in Kidney Function (95% CI) [a]	Estimated Rate at 5 Years [b] (95% CI)
Low	140	4.3% (1.6% - 9.1%)	4.9% (2.2% - 10.7%)
Moderate	82	18.3% (10.6% - 28.4%)	22.1% (13.6% - 34.6%)
High	18	50.0% (26.0% - 74.0%)	83.9% (52.4% - 98.9%)

[a] Exact Binomial confidence interval.
[b] Failure estimates and corresponding confidence interval from Kaplan-Meier analysis.

Figure 5. Kaplan-Meier curve for progressive decline in kidney function over time up to a maximum follow-up of 5 years in individuals self-identified as Black or African American ancestry.



Numbers at Risk

KidneyIntelX.dkd Level	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
Low	234	226	193	160	115	9
Moderate	146	132	102	77	55	5
High	37	26	17	6	6	2

KidneyIntelX.dkd Level	Number of Subjects	Percent of Patients Experiencing Progressive Decline in Kidney Function (95% CI) [a]	Estimated Rate at 5 Years [b] (95% CI)
Low	234	4.7% (2.4% - 8.3%)	6.6% (3.6% - 11.8%)
Moderate	146	15.8% (10.3% - 22.7%)	21.2% (14.4% - 30.6%)
High	37	37.8% (22.5% - 55.2%)	60.1% (39.1% - 81.7%)

[a] Exact Binomial confidence interval.
[b] Failure estimates and corresponding confidence interval from Kaplan-Meier analysis.

Figure 6. Kaplan-Meier curve for progressive decline in kidney function over time up to a maximum follow-up of 5 years in individuals self-identified of Non-Black or Non-African American ancestry.

Analytical Performance

The kidneyintelX.dkd biomarkers, KIM-1, TNFR-1, and TNFR-2 were validated appropriately for their use in the kidneyintelX.dkd algorithm and in accordance with applicable CLSI guidelines including those listed in Table 4 below.

Table 4. Analytical Performance of Biomarker Assays

Performance Characteristics	Reference
Detection Capability	CLSI Document EP17-A2[19]
Precision	CLSI Document EP05-A3[20]
Linearity	CLSI Document EP06-A[21]

Precision studies were conducted at Renalytix laboratory on the kidneyintelX.dkd biomarkers, including both repeatability (20-day precision study) and reproducibility studies (3 lots of kidneyintelX.dkd biomarker reagents and 3 MESO SECTOR® S 600 instruments). The maximum imprecision observed in these studies was 13% CV for KIM-1, 13% CV for TNFR-1, and 10% CV for TNFR-2.

Simulation studies were performed to evaluate the potential impact on the kidneyintelX.dkd test result due to the imprecision in measurement of inputs to the kidneyintelX.dkd test. All input variables for all participants in the clinical validation cohort (n=657) were simultaneously and randomly varied based on the measured or expected precision profile for each feature (n=100) for a total of 65700 simulations. The levels of imprecision evaluated were based on imprecision studies performed at Renalytix for the three biomarkers (KIM-1, TNFR-1, TNFR-2) and published data for the clinical variables (UACR, HbA1c and BUN). The outcome of these simulation studies did not result in an unacceptable impact on the overall clinical performance of the kidneyintelX.dkd test.

Analytical Specificity

Interfering Substances

Interference testing was performed according to CLSI EP07-Edition 3[22] and EP37-Edition 1[23] using pooled human K_2EDTA plasma samples. Interferents were selected from medications, common plasma interferents, and concentrations that were selected based on the CLSI guidelines and expected values for the patient population. Testing demonstrated no significant interference, defined as ≤± 10% change in the measurements of KIM-1, TNFR-1, and TNFR-2, for each of the following substances in Table 5.

Table 5. Interfering Substances Testing Summary

Test Substance	Highest Concentration Tested	Units
| Drugs and Other Substances		
Acetaminophen	15.6	mg/dL
Adalimumab (Humira)	0.5	mg/mL
Ampicillin sodium	7.5	mg/dL
Aspirin (ASA)	3	mg/dL
Calcium carbonate (total)	30.9	mg/dL
Calcium dobesilate	4.5	mg/dL
Cefoxitin sodium	660	mg/dL
Cholecalciferol (Vitamin D3)	195	ng/mL
Cyclosporine	0.18	mg/dL
Dapagliflozin	1.25	mg/mL
Doxycycline hydrochloride	1.8	mg/dL
Eplerenone (Aldosterone antagonist)	0.0555	mg/dL
Ethinyl estradiol	750	pg/dL
Fluorescein	30	mg/dL
Glipizide (Sulfonylureas)	0.3	mg/dL
GLP-1R agonist	1.25	mg/mL
Heparin	330	units/dL
Ibuprofen	21.9	mg/dL
Insulin	900	pmol/L
Lixisenatide (GLP-1R agonist)	0.05	mg/mL
Metformin	4	mg/dL
Metronidazole	12.3	mg/dL
Progesterone	227.7	nmol/L
Rifampicin	4.8	mg/dL
Sertraline	0.0927	mg/dL
Sex Hormone Binding Globulin	435	nmol/L
Sitagliptin Phosphate (DPP-4i)	0.115	mg/dL
Theophylline	6	mg/dL
| Supplements		
Selenium (selenomethionine)	226	ng/mL
Vitamin C	5.25	mg/dL
Vitamin D	195	ng/mL
Vitamin E (Alpha Tocopheryl Acetate)	51	µg/mL
Vitamin B12 (Cyanocobalamin)	2034	ng/L
Vitamin B9 (Folic Acid)	36.6	µg/L
Zinc	360	µg/dL
| Endogenous Substances		
Triglyceride-Rich Lipoproteins	1500	mg/dL
Hemoglobin	0.5	g/dL
Total Protein	8.5	g/dL
Bilirubin (conjugated)	40	mg/dL
Bilirubin (unconjugated)	40	mg/dL
Glucose	1000	mg/dL
Blood urea nitrogen (BUN)	120	mg/dL
Creatinine	15	mg/dL
Uric Acid	23.5	mg/dL

Test Substance	Highest Concentration Tested	Units
Potential Cross-Reactants		
TNF-α protein	100	ng/mL
TNF-β protein	100	ng/mL
Heterophile Interference		
Human anti-mouse antibody (HAMA)	372.4	ng/mL
Rheumatoid Factor (RF)	665	IU/mL

Note: % observed interference = [Mean Assay result (Test Pool) – Mean Assay Result (Control Pool)Mean Assay Result (Control Pool) x 100

Specimens with selenium levels above 226 ng/mL may have falsely elevated results.

Interference >± 10% was observed for the measurements of KIM-1, TNFR-1, and TNFR-2 at the concentrations shown below for the following substances:

Potentially Interfering Substance	Interference Level %	Observed Interference
Total Protein	13 g/dL	23%
Rheumatoid Factor (RF)	997 IU/mL	-11%

The kidneyintelX.dkd test should not be used in patients with known elevation of total protein above 8.5 g/dL. The kidneyintelX.dkd test should not be used in patients with known elevation of RF above 665 IU/mL.

Simulation studies were performed to evaluate the cumulative interference impact from all algorithm inputs on the kidneyintelX.dkd test results. The outcome of these simulation studies did not result in an unacceptable impact on the overall clinical performance of the kidneyintelX.dkd test.

Electromagnetic Compatibility

The MESO SECTOR® S 600 instrument has been tested by an independent accredited testing laboratory and found to comply with IEC 60601-1-2 (ed 4.0). Verification of compliance was conducted to the limits and methods of CISPR 11 Class A.

It is designed for operation in a controlled electromagnetic laboratory environment. Compatible accessories include the Meso Scale provided PC and uninterruptable power supply. This testing provides assurance of reasonable protection against harmful interference or performance degradation (i.e. read time or signal function) when the instrument is operated within a controlled laboratory environment. The instrument generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instrument manual, may cause interference that affects instrument function.

Caution!	The MESO SECTOR® S 600 instrument has been tested for operation in a controlled electromagnetic environment. Transmitters of RF energy such as mobile (cellular) telephones should not be used in close proximity.
Caution!	To avoid interference from electrical transients, plug the computer, monitor, and instrument into outlets on the same circuit. If an uninterruptible power supply (UPS) is available, plug the computer, monitor, and instrument into the battery backup outlets.
Warning!	Although the MESO SECTOR® S 600 is shielded and grounded, laboratory personnel should never remove any instrument covers that would expose electrical circuits.

Technical Assistance

For customer support, please contact Client Services at 1-888-203-2725 or at clientservices@renalytix.com.

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