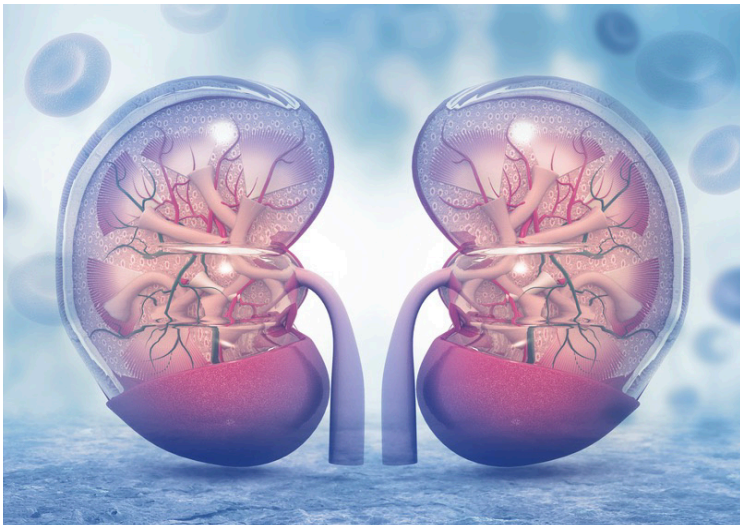


INTERPRETATION GUIDE

INNOVATIO ND2

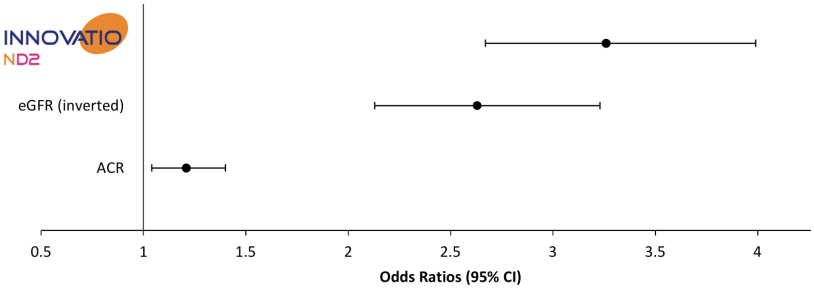
A blood test to assess risk of diabetic kidney disease (DKD) in patients with type 2 diabetes:

- Combines 3 biomarkers with 3 standard clinical factors
- **Predicts** risk of four-year onset of DKD before clinical symptoms appear
- Also diagnoses existing DKD that current tests may miss
- The only low-cost, high-speed prognostic test capable of predicting the onset of DKD

Prediction of Future Kidney Function Decline

Innovatio ND2 predicted DKD with a higher odds ratio compared to eGFR and ACR[1]

*DKD defined as incident diabetic kidney disease (eGFR <60mL/min/1.73m^2) in the next four years. If the eGFR level at the time of the test is already <60mL/min/1.73m^2, then the risk of a further decline in kidney function is defined as an eGFR decline ≥30% in the next four years.



Test Results

The test result is presented as 'low, moderate or high' risk, based on derived cut-off points.

Two Test Cut-off Points

Two test cut-off points were prospectively selected to optimise test performance:

- **Moderate risk** – provides optimal **sensitivity** to increase true positives
- **High risk** – provides optimal **specificity** to reduce false positives

Prognostic

- Estimates patient risk of **developing** DKD within the next four years, defined as *incident diabetic kidney disease* (eGFR <60mL/min/1.73m^2).
- If the patient's eGFR level at the time of the test is already <60mL/min/1.73m^2, then the risk of further kidney decline in the next four years, defined as an eGFR decline of ≥30%, is provided.

LOW RISK	MODERATE RISK	HIGH RISK
0% to <10% **Low four-year risk of developing DKD.**	**10% to <20%** **Moderate four-year risk of developing DKD.**	**20% to 100%** **High four-year risk of developing DKD.**
Standard diabetes monitoring. Retest annually.‡	Consider more frequent monitoring. Retest every 6 months.‡	Consider very close monitoring. Retest every 3 months.‡

- The prognostic risk score is determined using three biomarkers with three clinical factors (age, HDL-cholesterol and eGFR).
- Clinical studies have shown that the test predicted 86% of disease-free patients who went on to develop DKD within four years.[2]
- The test has a 98% negative predictive value (NPV), or "rule out" capability, that the patient will not develop DKD.[2]

Interpretation

Low Risk	Standard diabetes management; Status tested annually.‡
Moderate Risk	More frequent monitoring; Optimisation of lifestyle factors; Review of glycemic targets and management; Review of non-glycemic risk factors and their management including blood pressure and lipids; Avoidance of potentially nephrotoxic drugs; Utilisation of therapeutic drugs with evidence of renoprotection; Status tested every 6 months.‡
High Risk	Very close monitoring; Intensive management strategies based on those for 'Moderate risk' above with optimisation of treatments for diabetes and other risk factors. Status tested every 3 months.‡

Diagnostic

- Estimates patient risk of currently having DKD, defined as CKD stage ≥1 (ACR ≥30mg/g and/or eGFR <60mL/min/1.73m^2).[3]
- ≥30% indicates current kidney disease. Recommend to monitor eGFR and ACR levels.
- The diagnostic risk score is determined using three biomarkers with two clinical factors (age and HDL-cholesterol).
- The test identified 87% of patients having DKD.

For additional information please visit *www.innovatio-nd2.com*

eGFR – estimated glomerular filtration rate. ACR – albumin to creatinine ratio. SoC – Standard of Care.

‡Based on the ADA Standards of Medical Care in Diabetes 2022. American Diabetes Association Professional Practice Committee. 11. Chronic kidney disease and risk management: Standards of Medical Care in Diabetes—2022. Diabetes Care 2022;45(Suppl. 1):S175–S184.

[1]Peters KE, et al. A Comparison of PromarkerD to Standard of Care Tests for Predicting Renal Decline in Type 2 Diabetes. Poster presented at ASN Kidney Week. 2021.

[2]Peters KE, et al. Validation of a Protein Biomarker Test for Predicting Renal Decline in Type 2 Diabetes: The Fremantle Diabetes Study Phase II. J Diab Comp. 2019.

[3]KDIGO 2012 Clinical practice guideline for the evaluation and management of chronic kidney disease. Kidney International Supplement 2013; 3:1-150.

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