




**Renasight™**  
Kidney gene panel

A woman with dark, curly hair is shown in profile, looking upwards and to the right with a slight smile. She is wearing a light blue t-shirt. The background is a blurred outdoor scene with green foliage.

**Genes  
have  
a lot  
to say**

Providing insights  
with genetic testing  
for chronic kidney  
disease

# Introducing a new tool for the management of chronic kidney disease (CKD)

**Renasight™ is a kidney gene panel for patients who have been diagnosed with or who have a family history of CKD.**

Renasight has been designed for seamless integration into clinical practice:

- Leverages next-generation sequencing and other methodologies on more than **380 genes** associated with monogenic disorders linked to adult CKD
- Identifies autosomal dominant, autosomal recessive, and X-linked disorders
- Reports out on pathogenic and likely pathogenic variants that were hand-selected by genetics experts to provide actionable information
- Results available within **two to three weeks**



# Renasight provides valuable information for patient management



**Gain prognostic insight**



**Test family members and offer genetic counseling**



**Identify an etiology for patients with unknown cause of their CKD**



**Prescribe targeted therapies**



**Refer patients earlier for extra-renal features**



**Enroll patients in clinical trials**

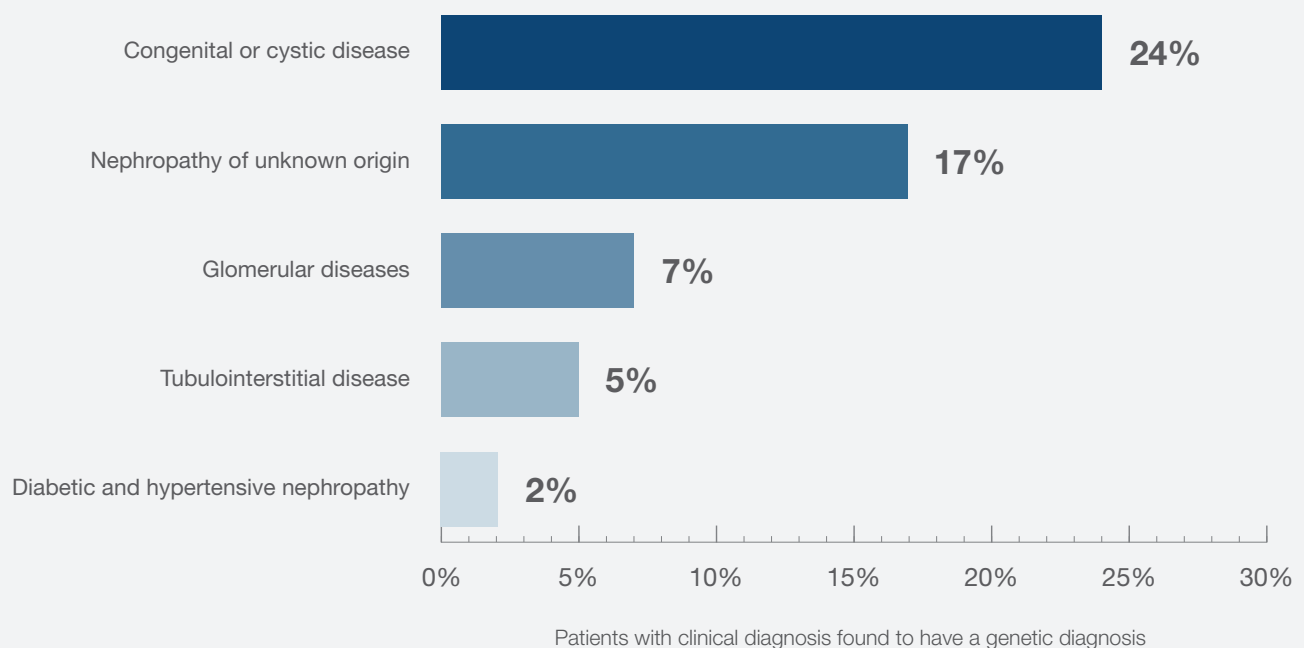
# Built on evidence

A recent *New England Journal of Medicine* publication assessing the incidence of genetic disease in a CKD population found **~1 in 10 patients** have a genetic diagnosis.



## Pinpoint and plan

Detected diagnostic variants in **9.3%** of 3315 patients with CKD and ESRD<sup>1</sup>

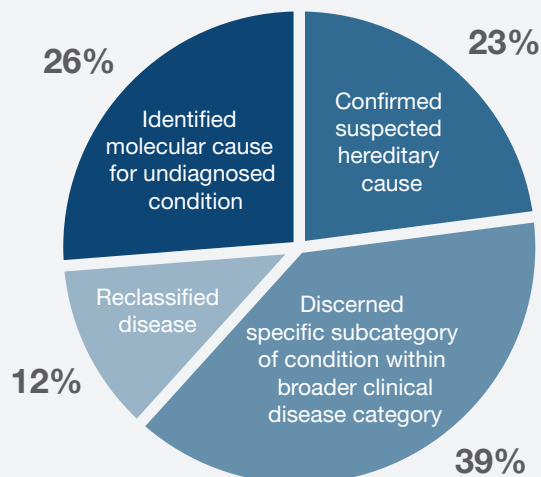




“This yield is similar to that observed for [hereditary] cancer, for which genomic diagnostics are **routinely used.**”<sup>1</sup>

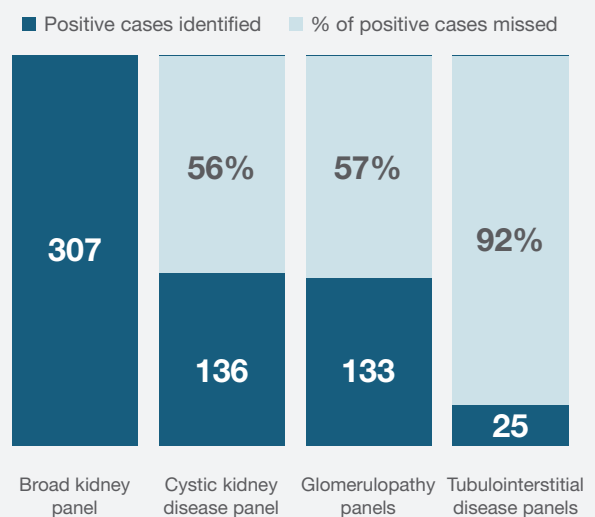
## Manage CKD with more information

In **89%** of patients with CKD, a genetic diagnosis had implications for clinical management



## Benefit with a broad panel

Targeted panels miss roughly **56%–92%** of positive cases, compared to a broad panel\*



\*A broad panel was compared to commercially available targeted panels to determine the number of cases identified by the broad panel that targeted panels would potentially be unable to identify.

## Improved prognostication of polycystic kidney disease (PKD) progression with genetics<sup>2</sup>

### PKD1/PKD2 mutation-positive

PKD1 Truncating mutations	PKD1 Non-truncating mutations	PKD2
58 Average age of ESRD onset	67 Average age of ESRD onset	79 Average age of ESRD onset
Earlier progression of ESRD by up to 20 years, depending on mutation		



### PKD1/PKD2 mutation-negative

- **6%–11%** of patients with clinical autosomal dominant PKD (ADPKD) **are negative for mutations in PKD1 or PKD2.**
- Other conditions may present with features similar to PKD but have different disease progression and risks to family members. Genetic testing can distinguish classic ADPKD from other cystic conditions for a more complete clinical picture.




## Individualize patient care with common inherited disorders

### Enhanced insight for glomerular disease<sup>3,4</sup>

#### COL4A3, COL4A4, COL4A5 MUTATIONS

Disease	Utility		
Focal segmental glomerulosclerosis (FSGS)	Identification of a genetic cause for nephrotic syndromes can prevent unnecessary immunosuppression.		
Thin basement membrane disorder (TBMD)	Heterozygous carriers rarely progress to more advanced CKD or ESRD.		
Alport syndrome	Establish a diagnosis in individuals without extra-renal manifestations; determine inheritance pattern for genetic counseling.		

## Clear clinical utility for disease management

Disease	Utility	
Primary Hyperoxaluria (PH1, PH2, PH3)	Three forms of PH have been identified, and are associated with different enzyme-producing genes. Specific mutations within these genes may also affect disease severity. Timely diagnosis of PH1 is essential to slow progression, manage medications, and provide appropriate pre-transplant workup. <sup>5</sup>	
Fabry disease	X-linked disorder with ESRD typical in the third to fifth decade for males, and variable presentation in females. Early diagnosis can lead to testing of at-risk relatives, enzyme-replacement therapy, and referrals to other specialists. <sup>6</sup>	

actionable clinical insights for  
and **less-frequent disorders**

## Applicable for patients being evaluated for kidney transplant

Up to **30%** of patients have end-stage renal disease of unknown etiology



### Assess risk of recurrence

C3 glomerulopathy (C3G)\*



### Accurate diagnosis

FSGS\*



### Provide treatment info

aHUS\*

Disease examples

\*KDIGO Clinical Practice Guideline on the Evaluation and Management of Candidates for Kidney Transplantation.

# Natera is committed to supporting you



## We welcome all insurance plans

and provide affordable testing through a variety of payment methods.

### How much will it cost?

- **Compassionate Care Program:** Natera proactively verifies eligibility for all patients. Patients who meet criteria will owe between \$0-149, based on federal income criteria. Patients who aren't eligible for the Compassionate Care Program will generally have an out-of-pocket responsibility of \$0-\$349 depending on their plan.
- **Commercial Insurance:** To protect against unexpected costs, Natera will estimate a patient's out-of-pocket cost and if it exceeds \$349 the patient will be contacted to discuss discounted cash pay options as an alternative to billing insurance.
- **Government Insurance (Medicare and Medicaid):** We do not expect patients to have any out-of-pocket expense.

## Access board-certified genetic counselors

Natera has more than 50 certified genetic counselors who are available to answer any provider or patient questions.

Patients can schedule a complimentary information session with a board-certified genetic counselor before or after their Renasight test.



## Discover multiple sample options

Natera accepts both blood and saliva samples. Collection kits can be shipped directly to the patient.

### REFERENCES

- 1 Groopman EE, Marasa M, Cameron-Christie S, et al. Diagnostic utility of exome sequencing for kidney disease. *N Engl J Med*. 2019;380(2):142-51.
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- 4 Stockman M, Renkema K, Giles R et al. The expanding phenotypic spectra of kidney diseases: insights from genetic studies. *Nat Rev Nephrol*. 2016 Aug;12(8):472-83.
- 5 Hopp K, Cogal A, Bergstralh E et al. Phenotype-Genotype Correlations and Estimated Carrier Frequencies of Primary Hyperoxaluria. *J Am Soc Nephrol*. 2015 Oct; 26(10): 2559-2570.
- 6 Mehta A and Hughes D. Fabry Disease. *GeneReviews*(R) ncbi.nlm.nih.gov/books/NBK1116/?term=fabry

201 Industrial Road, Suite 410, San Carlos, CA 94070 | Main +1 650.425.4005 | Fax +1 650.412.1974

The test described has been developed and its performance characteristics determined by the CLIA-certified laboratory performing the test. The test has not been cleared or approved by the US Food and Drug Administration (FDA). Although FDA has generally not enforced the premarket review and other FDA legal requirements for laboratory-developed tests in the US, certification of the laboratory is required under CLIA to ensure the quality and validity of the tests. CAP accredited, ISO 13485, and CLIA certified.

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