



NEWS RELEASE

New Paper Highlights Clinical Utility of Natera's Renasight™ Test in the Management of Kidney Disease

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AUSTIN, Texas--(BUSINESS WIRE)-- **Natera, Inc.** (NASDAQ: NTRA), a global leader in cell-free DNA testing, today announced the publication of a new paper in *Pediatric Nephrology*, which highlights the clinical utility of Renasight™ in aiding the diagnosis and management of kidney disease. The publication can be found [here](#).

This paper reviews the case of a 16-year-old patient with sickle cell disease (SCD) and kidney cysts. Natera's Renasight test, a genetic testing panel that analyzes 385 genes related to kidney disease, was administered to examine whether an additional genetic cause may have been contributing to the patient's kidney cysts. The test identified genetic variants which led to a diagnosis of autosomal dominant polycystic kidney disease (ADPKD), in addition to the patient's SCD.

SCD and ADPKD are distinct genetic conditions that affect kidney function. SCD is routinely diagnosed in newborns whereas ADPKD is most often diagnosed in adulthood. While both conditions may include the presence of kidney cysts, the two conditions have different treatment regimens and complications. Furthermore, there is the potential that treatments effective in one condition may be harmful to the other.

"In identifying the presence of these two conditions, genetic testing has provided crucial information impacting how we will monitor and treat this patient," said Asifhusen Mansuri, MD, Pediatric Nephrologist with Augusta University Medical Center. "We would not typically be looking for ADPKD in patients like this, and had it not been for this test, the patient's ADPKD might have gone undiagnosed. Genetic testing is providing care teams with key insights that will better inform disease management and potentially slow disease progression for patients with kidney disease."



Chronic kidney disease affects more than 10% of the global population. The New England Journal of Medicine published a study¹ in 2019 showing that 89% of patients with positive findings on a multi-gene genetic test had actionable clinical implications.

“This paper brings awareness to the complex nature of managing patients with dual monogenic conditions and the benefit to using broad-panel genetic testing,” said Sangeeta Bhorade, MD, Chief Medical Officer of Organ Health at Natera. “To our knowledge, this manuscript is the first report of an individual with both sickle cell disease and polycystic kidney disease, and as such, reporting additional cases of dual diagnoses will help deepen understanding of disease course and optimize treatment strategies.”

The clinical utility of Renasight is also being studied in a real world, prospective, multi-center clinical study called RenaCARE (Renasight Clinical Application, Review and Evaluation). The study includes more than 1,600 patients across 30+ sites, representing leading academic and private nephrology clinics in the U.S.

“Genetic testing presents a significant opportunity to improve the clinical management of diverse kidney diseases in both adults and children,” said Matthew Sampson, MD, MSCE, Associate Professor of Pediatrics at Harvard Medical School, Staff Nephrologist at Boston Children’s Hospital, Associate Member of the Broad Institute and a member of the Natera Scientific Advisory Board. “The eventual results of the RenaCARE study should help nephrologists and patients across the U.S. to more precisely understand the clinical utility of expanded genetic testing for kidney diseases such as that provided by Renasight.”

Preliminary results from the RenaCARE study will be presented at the National Kidney Foundation’s Spring Clinical Meetings in April, and a publication for the study is expected to be submitted in early 2023.

About Renasight

The Renasight™ test is a germline genetic test that screens for hereditary causes of kidney disease. It is indicated for patients with diagnosed kidney disease and is run from a patient's blood or saliva sample. Providers can use the Renasight test to identify a genetic predisposition, clarify a clinical diagnosis, or identify the etiology of an unknown kidney disease to help inform medical management. Additionally, genetic counseling and familial testing can be offered based on the test result. The test 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 U.S. Food and Drug Administration (FDA). CAP accredited, ISO 13485 certified, and CLIA certified.

About Natera

Natera™ is a global leader in cell-free DNA testing, dedicated to oncology, women’s health, and organ health. We

aim to make personalized genetic testing and diagnostics part of the standard of care to protect health, and inform earlier, more targeted interventions that help lead to longer, healthier lives. Natera's tests are validated by more than 100 peer-reviewed publications that demonstrate high accuracy. Natera operates ISO 13485-certified and CAP-accredited laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) in Austin, Texas and San Carlos, California. For more information, visit www.natera.com.

Forward-Looking Statements

All statements other than statements of historical facts contained in this press release are forward-looking statements and are not a representation that Natera's plans, estimates, or expectations will be achieved. These forward-looking statements represent Natera's expectations as of the date of this press release, and Natera disclaims any obligation to update the forward-looking statements. These forward-looking statements are subject to known and unknown risks and uncertainties that may cause actual results to differ materially, including with respect to whether the results of clinical or other studies will support the use of our product offerings, the impact of results of such studies, our expectations of the reliability, accuracy and performance of our tests, or of the benefits of our tests and product offerings to patients, providers and payers. Additional risks and uncertainties are discussed in greater detail in "Risk Factors" in Natera's recent filings on Forms 10-K and 10-Q and in other filings Natera makes with the SEC from time to time. These documents are available at www.natera.com/investors and www.sec.gov.

References

1. Groopman EE, Marasa M, Cameron-Christie S, et al. Diagnostic Utility of Exome Sequencing for Kidney Disease. *N Engl J Med*. 2019; 380:142-151 DOI: 10.1056/NEJMoa1806891

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