

### Explore a new technology for more-informed rejection assessment

Join us in understanding how the quantification of background cell-free DNA (cfDNA) may facilitate more precise rejection assessment and flag patients at high risk for false-negative interpretations.

A Study For KIDNEY TRANSPLANT PATIENTS

The PEDAL Study

#### The PEDAL Study for Kidney Transplant Patients

Prospera Enhancement by Detecting Background Cell-free DNA Levels

#### **PEDAL Study**

Together with our study collaborators, we hope to gain a better understanding of how quantifying the absolute concentration of background cell-free DNA (cfDNA) may allow for a more precise and confident assessment of allograft rejection—especially in identifying patients at-risk of false-negative interpretations.



## Let's understand how to more precisely assess for active rejection

Prospera<sup>™</sup> and the PEDAL Study will delve deeper into how to better manage your transplant patients using cfDNA as a non-invasive biomarker for active rejection. The study will include 500 kidney transplant patients from 20 major U.S. centers to measure diagnostic capability of the update across three critical measures:

1 Performance in both clinically indicated and surveillance biopsies Ability to identify both antibody mediated rejection and T cell-mediated rejection

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3 Correlation against clinical and/or histological resolution of rejection

#### Prospera's core technology

Leveraging our findings from two million cfDNA tests, Prospera is designed to assess kidney transplant injury by evaluating the percentage of donor-derived cell-free DNA (dd-cfDNA) in a transplant recipient's blood. Too much dd-cfDNA in the recipient's blood is an early indication of potential organ rejection.



Based on our leadership in cfDNA innovation, Natera has now introduced two novel techniques for even greater precision in Prospera results:



#### PEDAL STUDY ELIGIBILITY

Inclusion Criteria

Must be willing to provide informed consent Must be a kidney transplant recipient Exclusion Criteria

Cannot have other non-kidney transplanted organ(s) Cannot be pregnant

Cannot have genetically identical donor organs

# We need your help to enable patients to thrive and prosper

With Prospera, we delivered a non-invasive way to identify rejection, giving you greater confidence in making treatment decisions for your organ transplantation patients. But we can do more—we're committed to continue refining this test to support you in bringing hope to these patients. Starting now.

Through PEDAL and other studies, we look to you as our partner in delivering innovations that offer a second chance to patients. Because together, we can make meaningful changes—in individual lives and the field of organ transplantation.

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. © 2020 Natera, Inc. All Rights Reserved. PRO\_MD\_BR\_PEDALStudy\_2020529\_NAT-8020163

For more information, visit: natera.com/prospera pedal@natera.com



<sup>1</sup> Organ Donation Statistics. U.S. Department of Health and Human Services. U.S. Government Information on Organ Donation and Transplantation. https://www.organdonor.gov/statistics-stories/statistics.html. Published March 31, 2016.

<sup>2</sup> Kidney Disease Statistics for the United States. National Institute of Diabetes and Digestive and Kidney Diseases.

https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease. Published Dec. 1, 2016.

<sup>3</sup> Stegall et al, Through a Glass Darkly: Seeking Clarity in Preventing Late Kidney Transplant Failure, J Am Soc Nephrol. 2015; 26 (1):20-9 4 Lamb et al, Long-term renal allograft survival in the United States: a critical reappraisal, Am J of Transplantation. 2011; Mar;11(3):450-62.5. Altug, et al.

<sup>5</sup> Sigdel TK, et al. J. Clin. Med. 2019, 8, 19.

### The PEDAL Study for Kidney Transplant Patients Prospera Enhancement by Detecting Background cfDNA Levels

A kidney transplant is the greatest gift that can be given or received. Such a precious treasure must be cared for with the utmost diligence and attention.

A precise, non-invasive biomarker for rejection gives you the confidence you need to know that all is well. Natera will continue to refine and improve Prospera now and in the future. We understand the importance of caring for patients and will always be your best partner.



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## Prospera™<br/>Transplant assessment

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