



NEWS RELEASE

# Natera Launches Differentiated New Feature for Prospera™ Heart Test, Enhancing Detection of Rejection for Transplant Patients

6/17/2024

Donor Quantity Score (DQS) technique is unique to Natera, improving detection of both acute cellular rejection and antibody-mediated rejection

AUSTIN, Texas--(BUSINESS WIRE)-- **Natera, Inc.** (NASDAQ: NTRA), a global leader in cell-free DNA (cfDNA) and genetic testing, today announced the launch of Prospera Heart™ with Donor Quantity Score (DQS), further enhancing Prospera's ability to detect rejection in heart transplant patients.

Traditionally, donor-derived cell-free DNA (dd-cfDNA) tests have reported rejection risk based only on the fraction of dd-cfDNA in the blood vs. the total cfDNA (dd-cfDNA %). This fraction can be confounded by fluctuations in the amount of background total cfDNA (the denominator), which are sometimes caused by factors unrelated to the health of the transplant, including infection, surgery, or chemotherapy.

Prospera Heart now incorporates a second metric – the DQS – that normalizes for the background total cfDNA. Prospera Heart with DQS combines the traditional donor fraction and the new DQS into a two-threshold algorithm, delivering a single result with more accurate risk assessment for both antibody mediated rejection (AMR) and acute cellular rejection (ACR).

“Over the last two decades, Natera has pioneered cfDNA testing across women’s health, oncology, and transplant medicine,” said Michael Olymbios, M.D., Medical Director, Heart Transplant. “Our extensive experience with cfDNA and Natera’s culture of continuous innovation drove us to further refine Prospera Heart by introducing this two-



threshold algorithm to better serve the transplant community.”

A study performed at the University of Utah and the University of California San Diego showed that incorporating DQS enhanced the performance of Prospera Heart in screening for biopsy-proven active rejection. In an initial analysis of 703 plasma samples, the two-threshold algorithm, as compared to the traditional dd-cfDNA % alone, improved several key performance metrics as follows:

- Sensitivity increased from 80.0% to 88.2%
- Specificity increased from 76.1% to 84.2%, reducing false positive results by 37.5%
- Increased negative predictive value (NPV) from 97.4% to 98.6%

The **study** was presented at The International Society for Heart and Lung Transplantation’s annual meeting in April 2024, and it will be submitted for peer-reviewed publication later this year.

“The initial findings from our study indicate that DQS complements donor fraction and provides a clearer picture of rejection risk for the patient, compared to donor fraction alone,” said Josef Stehlik, M.D., M.P.H., Medical Director of the Heart Transplant Program and Co-chief of the Advanced Heart Failure Program at the University of Utah Hospital. “We believe this innovative technique can lead to fewer unnecessary biopsies and follow-up procedures for heart transplant recipients given the increase in sensitivity.”

A similar two-threshold dd-cfDNA test for assessing the risk of kidney transplant rejection, Prospera Kidney with Quantification, was published in the **Journal of the American Society of Nephrology** 1 and has been offered by Natera for kidney transplant patients since 2021.

## About Prospera

The **Prospera™** test leverages Natera’s core single-nucleotide (SNP)-based massively multiplexed PCR (mmPCR) technology to identify allograft rejection non-invasively and with high precision and accuracy, without the need for prior donor or recipient genotyping. The test works by measuring the fraction of donor-derived cell-free DNA (dd-cfDNA) in the recipient’s blood. It may be used by physicians considering the diagnosis of active rejection, helping to rule in or out this condition when evaluating the need for diagnostic testing or the results of an invasive biopsy. The Prospera test has been clinically and analytically validated for performance regardless of donor relatedness, rejection type, and clinical presentation.

## About Natera

Natera™ is a global leader in cell-free DNA and genetic 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 200 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](http://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, or our expectations 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](http://www.natera.com/investors) and [www.sec.gov](http://www.sec.gov).

## References

1. Bunnapradist S, Homkrailas, P, Ahmed, E, et al. Using both the fraction and quantity of donor-derived cell-free DNA to detect kidney allograft rejection, J Amer Soc Nephrology 2021; 32(10): 2439-2441.

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Source: Natera, Inc.