



NEWS RELEASE

# Natera Supports Updated ISHLT Guidelines for the Care of Heart Transplant Patients

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AUSTIN, Texas--(BUSINESS WIRE)-- **Natera, Inc.** (NASDAQ: NTRA), a global leader in cell-free DNA (cfDNA) testing, announced its support for a recent guideline update by the International Society for Heart and Lung Transplantation (ISHLT), which includes the use of donor-derived cfDNA (dd-cfDNA) testing for surveillance of heart transplant recipients. The updated ISHLT guidelines, which were last revised in 2010, were published today in the *Journal of Heart and Lung Transplantation*<sup>1</sup>.

In the newly updated guidelines, ISHLT includes dd-cfDNA testing in a Class I, Level B recommendation covering the suggested components for ongoing rejection monitoring in heart transplant recipients. The recommendation proposes monitoring for rejection (with noninvasive biomarkers or biopsy) monthly during the first six months post transplant, as well as testing in the 9th and 12th months post transplant.

"We commend ISHLT on these recently updated guidelines that will undoubtedly help improve and standardize care management for heart transplant recipients," said Dr. Sangeeta Borhade, chief medical officer for organ health at Natera. "This important change is a testament to the data supporting dd-cfDNA testing for heart transplant patients, and we remain committed to generating robust scientific evidence to improve care for transplant patients."

Natera launched the Prospera™ Heart dd-cfDNA test in late 2021. The clinical validation study of 811 samples from 223 patients from the multi-site DEDUCE study was published in 2022 in the *Journal of Heart and Lung Transplantation*<sup>2</sup>. The Prospera Heart test was also evaluated in the NIH-supported DTRT study (publication to be submitted early 2023).



## About the Prospera test

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. It has been developed and its performance characteristics determined by Natera, the CLIA-certified laboratory performing the test. The test has not been cleared or approved by the US 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](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. Velleca A, Shullo MA, Dhital K, et al. The International Society for Heart and Lung Transplantation (ISHLT) Guidelines

for the Care of Heart Transplant Recipients. J Heart Lung Transplant. 2022.

**<https://doi.org/10.1016/j.healun.2022.10.015>**.

2. Kim PJ, Olymbios M, Siu A, et al. A novel donor-derived cell-free DNA assay for the detection of acute rejection in heart transplantation. J Heart Lung Transplant. 2022 Jul;41(7):919-927.

Investor Relations: Mike Brophy, CFO, Natera, Inc., 510-826-2350, **[investor@natera.com](mailto:investor@natera.com)**

Media: Lesley Bogdanow, VP of Corporate Communications, Natera, Inc., **[pr@natera.com](mailto:pr@natera.com)**

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