



Natera Publishes Largest NIPT Outcomes Study Demonstrating Robust Clinical Performance Over a 4-year Period

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High positive predictive value shown for common chromosomal aneuploidies in all women, including women under 35 years of age

SAN CARLOS, Calif., Sept. 9, 2019 /PRNewswire/ -- [Natera, Inc.](#) (NASDAQ: NTRA), a global leader in cell-free DNA testing, today announced the publication of the largest non-invasive prenatal test (NIPT) outcomes study to date, analyzing its Panorama[®] assay over a 4-year period. The primary objective of the study, published in the *Journal of Clinical Medicine*,¹ was to analyze prospectively the clinical performance of the company's NIPT as a part of its rigorous quality assurance program.



The study cohort included a total of 1,035,844 patients, of which 13,231 (1.3%) were high-risk patients whose fetal outcome data was solicited. The positive predictive value (PPV) in this cohort was 95% for trisomy 21 (Down syndrome), and similar for both high-risk (maternal age ≥ 35 yrs) and average-risk (< 35 yrs) pregnancies, consistent with a previous study ($n=17,885$).²

"This latest publication reinforces our commitment to quality and rigor in test performance. Panorama now has a market-leading 19 peer-reviewed publications with 1.2 million patients, which is twice the number of patients in published studies from all other primary NIPT companies combined," said Ramesh Hariharan, General Manager of Natera's Reproductive Health business.

"Panorama's market leadership position is driven by clinical differentiation including published evidence of the lowest false negative and false positive rates, the unique ability to detect triploidy and vanishing twins, and the ability to determine zygosity in twin pregnancies. This recent study further strengthens the evidence base that supports the core clinical claims," said Dr. Russ Jelsema, Medical Director of Natera's Reproductive Health business. "Our commitment to ongoing innovation is reflected in the SMART (SNP-based Microdeletion and Aneuploidy Registry Trial) study, which has enrolled 20,000 patients and is expected to read out in 2020."

About Natera

[Natera](#) is a global leader in cell-free DNA testing. The mission of the company is to change the management of disease worldwide with a focus on reproductive health, oncology, and organ transplantation. Natera operates an ISO 13485-certified and CAP-accredited laboratory certified under the Clinical Laboratory Improvement Amendments (CLIA) in San Carlos, Calif. It offers a host of proprietary genetic testing services to inform physicians who care for pregnant women, oncologists, and cancer researchers, including biopharmaceutical companies, and genetic laboratories through its cloud-based software platform. For more information, visit [natera.com](#). Follow Natera on [LinkedIn](#).

About Panorama[®]

[Panorama](#) reveals a baby's risk for severe genetic disorders as early as nine weeks into pregnancy. The test uses a unique single-nucleotide polymorphism (SNP)-based technology to analyze fetal/placental DNA obtained through a blood draw from the mother. It is the only test that differentiates between maternal and fetal DNA in the relevant chromosomes of interest. The test also screens twin pregnancies for zygosity, fetal sex of each baby, and identifies risk for more genetic conditions in twin pregnancies than any other NIPT. Panorama is one of several genetic screening tests from Natera designed to help families on the path to parenthood.

This test was developed by Natera, Inc., a laboratory certified under the Clinical Laboratory Improvement Amendments (CLIA). This test has not been cleared or approved by the U.S. Food and Drug Administration (FDA). Although FDA does not currently clear or approve laboratory-developed tests in the U.S., certification of the laboratory is required under CLIA to ensure the quality and validity of the tests.

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 our efforts to develop and commercialize new product offerings, our ability to successfully increase demand for and grow revenues for our product offerings, whether the results of clinical studies will support the use of our product offerings, our expectations of the reliability, accuracy and performance of our screening tests, or of

the benefits of our screening 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.

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2. Dar P, Curnow KJ, Gross SJ, et al. Clinical experience and follow-up with large scale single-nucleotide polymorphism-based noninvasive prenatal aneuploidy testing. *Am J Obstet Gynecol*. 2014;211(5):527.e1-527.e17.

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