



NEWS RELEASE

Natera Launches Fetal Focus™: A Noninvasive Prenatal Test for Inherited Conditions

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Launch supported by strong assay performance in first milestone readout of the landmark EXPAND clinical trial

AUSTIN, Texas--(BUSINESS WIRE)-- Natera, Inc. (NASDAQ: NTRA), a global leader in cell-free DNA (cfDNA) testing and precision medicine, today announced the launch of Fetal Focus, a noninvasive prenatal test (NIPT) for inherited conditions.

When a pregnant patient is identified as a carrier of a recessive single-gene condition, medical guidelines recommend partner testing in order to determine the risk for the baby to be affected by the condition¹; however, in some cases the biological father is unavailable for testing. The Fetal Focus test was designed to address this unmet need. Now if a pregnant patient tests positive with Natera's Horizon™ carrier screen for one of the five most commonly tested genes, and if the father is unavailable for testing, Fetal Focus can screen the fetus directly for that gene by simply analyzing a sample of the mother's blood.

Fetal Focus is validated for the analysis of five genes: CFTR (cystic fibrosis), SMN1 (spinal muscular atrophy), HBA1 and HBA2 (alpha-thalassemia), and HBB (beta-hemoglobinopathies, including sickle cell disease).

The launch is supported by data from EXPAND, a large, prospective, blinded clinical trial. The study, which was initiated in 2023, has enrolled approximately 1,300 participants to date, reflecting a diverse, multi-ethnic population from leading academic medical centers and maternal fetal medicine clinics. EXPAND is designed to be the defining clinical trial in the category, with all outcomes, including both positive and negative results, confirmed by genetic truth using prenatal or postnatal diagnostic testing.

In its first milestone readout (n=101) from EXPAND, the Fetal Focus test demonstrated 91% sensitivity and successfully identified 5/5 fetuses affected by homozygous variants.^{2,3} Homozygous cases, where the fetus inherits the same condition-causing variant from both parents, are especially challenging to detect. Fetal Focus uses Natera's proprietary LinkedSNP™ technology to improve detection of these cases across diverse populations.

"Having access to a noninvasive option like Fetal Focus can provide critical information to support decision-making during pregnancy, especially in situations where partner testing isn't possible," said John Williams, M.D., chief principal investigator for EXPAND and director of reproductive genetics at Cedars-Sinai.

"Fetal Focus adds another important offering within our comprehensive reproductive health portfolio – furthering our commitment to launching products that address clinical gaps in care and are supported by rigorous clinical validation," said Sheetal Parmar, M.S., CGC, senior vice president of medical affairs for women's health at Natera. "The EXPAND study has been underway for several years, and we're pleased to release this first milestone readout."

References

1. ACOG Committee Opinion #690, Mar 2017.
2. Internal data on file. In EXPAND, the study participants and investigators are blinded to the Fetal Focus™ test results.
3. Expanding Prenatal Cell Free DNA Screening Across Monogenic Disorders (EXPAND). <https://clinicaltrials.gov/study/NCT06808880>. Accessed July 2025.

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 supported by more than 300 peer-reviewed publications that demonstrate excellent performance. 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.

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