



NEWS RELEASE

# Natera Launches 21-Gene Fetal Focus™ Single-Gene NIPT, Powered By Ultra-Sensitive LinkedSNP™ Technology

2026-01-05

Fetal Focus achieved 96% sensitivity and 98% specificity in validation from the prospective blinded EXPAND clinical trial

AUSTIN, Texas--(BUSINESS WIRE)-- **Natera, Inc.** (NASDAQ: NTRA), a global leader in cell-free DNA and precision medicine, today announced the launch of Natera's expanded 21-gene Fetal Focus single gene non-invasive prenatal test (sgNIPT), supported by new findings from the blinded prospective EXPAND clinical trial. Results from this analysis demonstrate the test's ability to detect a broader set of clinically relevant inherited conditions with high accuracy.

The latest readout from EXPAND included 193 prospectively-collected clinical samples associated with the 16 new genes in the panel. In this new cohort, Fetal Focus achieved 100% sensitivity (14/14) for identifying affected pregnancies and 94.2% observed specificity. Combined with data reported previously from the EXPAND trial, Fetal Focus has now demonstrated overall 96% sensitivity (24/25 affected pregnancies) and 98% population-weighted specificity in 294 total samples across the full 21 genes. These results represent the first prospective, blinded validation for an expanded set of conditions, with confirmatory diagnostic testing for all positive and negative cases.

Fetal Focus analyzes cell-free DNA circulating in maternal blood to assess whether a fetus has inherited disease-causing variants from one or both parents. The test is an option for pregnant patients who test positive with Natera's Horizon™ carrier screen when the father is unavailable for guideline-recommended carrier testing<sup>1</sup>. In addition to the initial five genes, the updated test incorporates 16 additional genes associated with severe or early-

onset disease, including Tay-Sachs disease, Gaucher disease, and galactosemia.

Launched in 2023, the EXPAND trial has enrolled more than 1,800 participants from leading academic medical centers and maternal-fetal medicine practices, reflecting a diverse, multi-ethnic population. In the initial readout, Fetal Focus correctly identified all five cases affected by homozygous variants<sup>2,3</sup>, a category that is particularly challenging because the fetus inherits the same disease-causing variant from both parents. Fetal Focus uses Natera's proprietary ultra-sensitive LinkedSNP™ technology to support detection of these cases across diverse populations.

"The updated panel gives clinicians access to information on a broader range of inherited conditions," said John Williams, M.D., chief principal investigator for EXPAND and director of reproductive genetics at Cedars-Sinai. "Because of the prospective design of this study and diagnostic confirmation of all outcomes, these latest results strengthen the evidence base needed for responsible integration of single-gene NIPT into clinical practice."

"Our goal is to support clinicians and families with actionable information at critical healthcare moments," said Sheetal Parmar, M.S., CGC, senior vice president of medical affairs, women's health at Natera. "The growing body of blinded, prospective data from EXPAND supports the case for Fetal Focus to fill an important clinical gap, particularly when partner testing is not possible."

## References

1. ACOG Committee Opinion #690, Mar 2017.
2. Internal EXPAND validation data. 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 December 2025.

## About Natera

Natera™ is a global leader in cell-free DNA and precision medicine, 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 325 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, and through Foresight Diagnostics, its subsidiary, operates an ISO 27001-certified and CAP-accredited laboratory certified under CLIA in Boulder, Colorado. 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, 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](http://www.natera.com/investors) and [www.sec.gov](http://www.sec.gov).

Investor Relations: Mike Brophy, CFO, Natera, Inc., [investor@natera.com](mailto:investor@natera.com)

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

Source: Natera, Inc.