SDx Labs

Prenactive™ Noninvasive Prenatal Screen

Gain early insights into your prenatal health

The Prenactive Noninvasive Prenatal Screen safely and noninvasively screens for the most common chromosomal conditions affecting pregnancies. This screen can be done as early as 10 weeks gestation using a single maternal blood draw and offers high detection rates, low false positive rates, and the lowest test failure rate in the industry.[1]

What is noninvasive prenatal screening (NIPS)?

NIPS is a type of blood test that identifies fragments of DNA from the pregnancy, known as cell-free DNA, in the mother's blood stream. The Prenactive Noninvasive Prenatal Screen uses whole-genome sequencing (WGS) to evaluate these cell-free DNA fragments and screen for common chromosomal conditions. It is now recommended that all patients be offered NIPS in their pregnancy, regardless of maternal age or other risk factors.

Benefits of NIPS

- Proven superiority to traditional screening methods with higher detection rates, reduced false positive rates.
  - Offers the highest reported detection rate for Down syndrome[4]
  - Offers the lowest reported false positive rate for Down syndrome[4]
- Offers the broadest screening window (performed as early as 10 weeks gestation until term)[4-6]
- Fast turnaround time[1]
- Lowest published failure rate in the industry, 0.1%[1-3]

The Prenactive™ Prenatal Screen offers screening for the following conditions:

- Trisomy 21 (Down syndrome)
- Trisomy 18 (Edwards syndrome)
- Trisomy 13 (Patau syndrome)
- Sex chromosome aneuploidy (X, XXX, XXY, and XYY) with predicted fetal sex can be added if requested

Clear, concise results

Each condition screened for on the Prenactive Noninvasive Prenatal Screen is reported individually with a "high-risk" or "low-risk" result. High-risk results indicate that there is increased concern for this condition in the pregnancy and a percentage (the positive predictive value) is given to indicate the chance the pregnancy is affected. Genetic counseling, ultrasound, and the option of diagnostic testing are recommended following a high-risk NIPS result. Low-risk results are very reassuring that the pregnancy is likely unaffected by that condition.

Limitations of the screen

Noninvasive prenatal screening (NIPS) is a screen; it is not diagnostic test. False positive and false negative results do occur. Further confirmatory testing is necessary prior to making any irreversible pregnancy decision. A negative result does not eliminate the possibility that the pregnancy has one of the conditions screened for. NIPS does not screen for other chromosomal conditions such as triploidy, birth defects such as open neural tube defects, single gene disorders, or other conditions, such as autism. There is a small possibility that the test results might not reflect the chromosomal status of the pregnancy, but may instead reflect chromosomal changes in the placenta, a demised twin, or the mother, that may or may not have clinical significance.

SDxLabs

About SDxLabs

SDxLabs delivers noninvasive diagnostic and women's health solutions that support proactive healthcare decisions. Our services focus on early detection and actionable results that enable effective treatments and improved patient outcomes. SDxLabs is committed to empowering patients, providers, and the community with access to relevant health services and unmatched service.

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References

1. Taneja PA, Snyder HL, de Feo E, et al. Noninvasive prenatal testing in the general obstetric population: clinical performance and counseling considerations in over 85 000 cases. Prenat Diagn. 2016;36(3):237-243.
2. McCullough RM, Almasri EA, Guan X, et al. Non-invasive prenatal chromosomal aneuploidy testing--clinical experience: 100,000 clinical samples. PLoS One. 2014;9(10):e109173.
3. Ryan A, Hunkapiller N, Banjevic M, et al. Validation of an enhanced version of a single-nucleotide polymorphism-based noninvasive prenatal test for detection of fetal aneuploidies. Fetal Diagn Ther. 2016;40(3):219-223.
4. Practice Bulletin No. 163: Screening for Fetal Aneuploidy. Obstet Gynecol. 2016;127(5):979-981.
5. Gregg AR, Skotko BG, Benkendorf JL, et al. Noninvasive prenatal screening for fetal aneuploidy, 2016 update: a position statement of the American College of Medical Genetics and Genomics. Genet Med. 2016;18(10):1056-1065.
6. Bianchi DW, Parker RL, Wentworth J, et al. DNA sequencing versus standard prenatal aneuploidy screening. N Engl J Med. 2014;370(9):799-808.