Category

Best Startup

Product/Solution Name

Juno Hazel™ Non-Invasive Screening

Date of Approval

N/A

Indications

Screening for sex chromosome aneuploidies and common fetal trisomy, including trisomy 21, trisomy 18, and trisomy 13, Juno Diagnostics' Hazel™ NIPS enables early detection and facilitates appropriate medical interventions to support positive maternal and fetal health outcomes.

Juno Hazel™ Plus screens for the following indications:
- Trisomy 21 (Down syndrome)
- Trisomy 18 (Edwards syndrome)
- Trisomy 13 (Patau syndrome)

Sex chromosome aneuploidies:
- Monosomy X (Turner syndrome)
- XXY syndrome (Klinefelter syndrome)
- Trisomy X (Triple X syndrome)
- XYY syndrome (Jacobs syndrome)

Therapeutic Categories

Women's Health, Prenatal Care, Reproductive Health

Attached Files:
- JunoDxHazelFlyerB2B.pdf

Background information and need for solution/product

Founded by the visionary team who launched the first commercially available non-invasive prenatal screening (NIPS) in the United States, MaterniT® 21, Hazel™ has emerged as a revolutionary solution in the field of prenatal screening. With a rich history of pioneering advancements, the Juno Diagnostics team embarked on a mission to improve access to high-quality tests and to provide affordable prenatal care. Hazel™, a capillary-based cfDNA screening test, stands as a testament to our dedication to excellence and innovation and our desire to create technology with proven medical utility.

NIPS, also known as NIPT, evaluates the risk of chromosomal abnormalities, offering a significantly lower false positive rate and minimizing invasive procedures compared to traditional serum screening. With its minimum false negative rates of less than 1% for common aneuploidies across high-risk and average-risk pregnancies, NIPS offers expectant parents vital health insights.

Traditionally, NIPS was recommended primarily for women aged 35 or older or those deemed high risk. However, the Society for Maternal-Fetal Medicine (SMFM) and the American College of Obstetricians and Gynecologists (ACOG) has recently changed guidelines regarding prenatal screening, now recommending that NIPS be offered to all women regardless of age or baseline risk. Despite such recommendations, barriers to NIPS access, such as cost and geographical location, exist.

Hazel™ NIPS leverages unique capillary-based cfDNA analysis with at-home convenience to ensure every pregnant woman can benefit from access to prenatal screening. In furtherance of the goals endorsed by SMFM and ACOG, Hazel™ addresses the need for reliable results in detecting chromosomal abnormalities, including Down syndrome, trisomy 18, and trisomy 13, while reducing the burden on expectant parents by facilitating the possibilities of a seamless at-home experience.

Attached Files:

- JunoDx_Whitepaper_EquitableNIPS.pdf

History of the development of the solution/product

Conceptualized as a means for enhancing the accuracy and accessibility of prenatal screening, Hazel™ was created to push the boundaries of technological advancement in prenatal care and beyond. Driven by a common goal of meeting patients' needs wherever they may be, the team behind the first commercial NIPS in the U.S. sought to redefine screening technology with equity in mind at Juno Diagnostics.

Hazel™ has undergone rigorous clinical evaluation, substantiating its efficacy and accuracy. Publications within the American Journal of Obstetrics & Gynecology (AJOG) provide comprehensive evidence of the effectiveness of Hazel™ as a reliable means of circumventing obstacles and disparities in access to NIPS. The clinical validation showcases how this capillary-based cfDNA analysis and its ability to provide valuable insights into fetal development offers a transformative experience for both healthcare providers and families.

Clinically validated with >99% sensitivity and >99.9% specificity, Hazel™ empowers expectant parents with the knowledge and confidence they deserve, while improving maternal health outcomes. From inspiration to its transformative realization, Hazel™ serves as a step forward in reshaping the future of prenatal care and fostering positive outcomes for expectant parents.

Why this solution/product is innovative, the broad implications for future research, and/or how it will improve the human condition

Built on a foundation of cutting-edge technology and driven by an unwavering commitment to improving the human condition, Hazel™ is a pivotal turning point in prenatal screening. Its advancements pave the way for transformative applications beyond the realm of prenatal health, offering new avenues for early detection and proactive interventions, including within the fields of organ health and oncology. By harnessing the power of advanced technology, the Hazel clinical platform promises to reshape the healthcare landscape, unlocking a future where timely interventions can improve health outcomes.

As the world's first capillary-based cfDNA screening test, Hazel™ introduces a paradigm shift in prenatal care, redefining accuracy, accessibility, and convenience. By harnessing the power of advanced technology, Hazel™ transcends traditional screening methods, offering expectant parents

unrivaled insights into the development of a fetus. Its innovative approach and exceptional performance push the boundaries of what is possible, setting new standards for prenatal screening worldwide.

Hazel™ serves as a catalyst for positive change, empowering expectant parents with knowledge and enabling informed decision-making. By offering accurate, affordable, and readily available information about fetal health, Hazel™ instills confidence, reduces anxiety, and fosters proactive prenatal care. The advanced technology contributes to healthier pregnancies, promotes early interventions, and ultimately improves the well-being of both parents and children. By expanding access to high-quality care and driving advancements in prenatal research, Hazel™ ensures a brighter future for generations to come.

Hazel™ encompasses a new standard for high-quality prenatal care while simultaneously opening the doors to groundbreaking advancements in other fields, including oncology and organ health. Its innovative technology, with its broad implications and transformative potential, promises to reshape the future of healthcare. By harnessing the power of capillary-based cfDNA analysis, Hazel™ ushers in a future where early detection, personalized interventions, and improved outcomes become the cornerstones of medical practice.

Attached Files:

- ACOJ_Juno_Publication.pdf

Please provide appropriate references (ie Pubmed links)

Ehrich, M., Sagaser, K. G., Porreco, R. P., Bellesheim, D., Patil, A. S., Shulman, L. P., & Van Den Boom, D. (2023). Capillary blood collection: Exploring a new method to promote noninvasive prenatal screening access. American Journal of Obstetrics and Gynecology. https://doi.org/10.1016/j.ajog.2023.03.008

Practice bulletin no. 163: Screening for fetal aneuploidy. (2016). Obstetrics & Gynecology, 127(5), e123–e137. https://doi.org/10.1097/aog.0000000000001406

Screening for fetal chromosomal abnormalities: ACOG practice bulletin summary, no. 226. (2020). Obstetrics & Gynecology, 136(4), 859–867. https://doi.org/10.1097/AOG.0000000000004107

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