



Now endorsed by
ACOG and SMFM
for all pregnancies
regardless of age
or risk¹

IT'S TIME FOR
NIPT
FOR ALL

GET ACCURATE PRENATAL INSIGHTS
AS EARLY AS WEEK 10.¹

ACOG=American College of Obstetricians
and Gynecologists; SMFM=Society for
Maternal-Fetal Medicine.

ACCURATE

EARLY

NONINVASIVE

FOR ALL PREGNANCIES

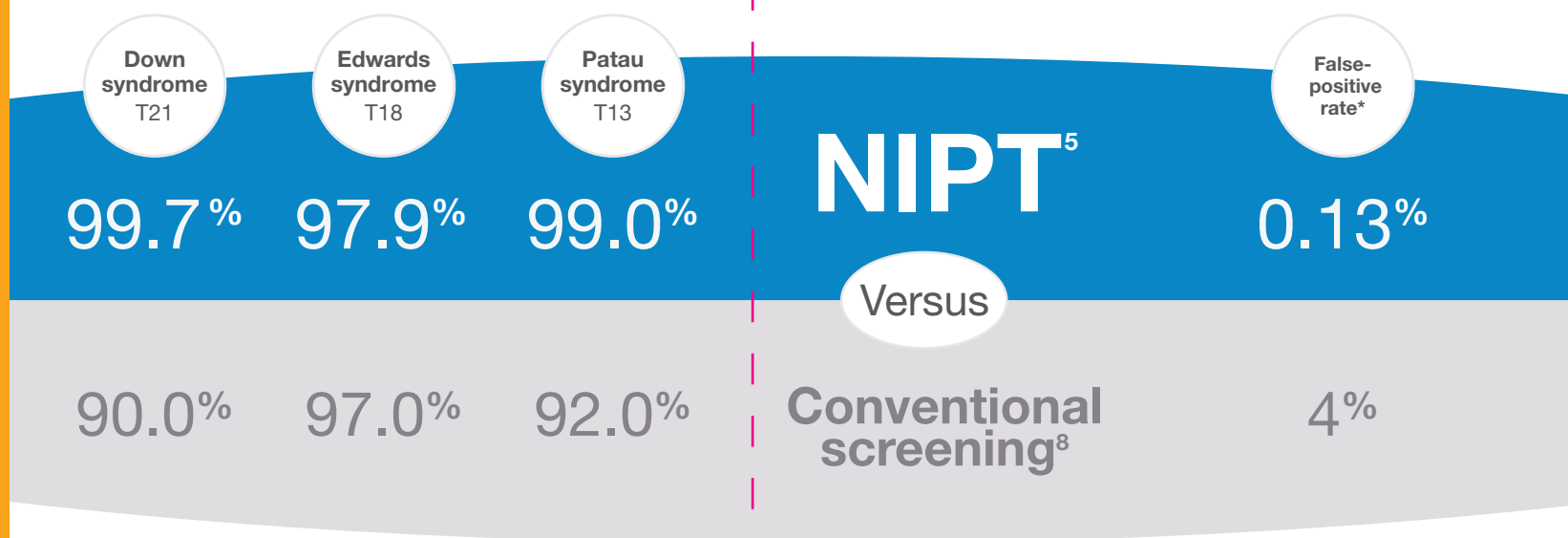


Accurate insights.
Recommended to
be offered to all.¹

In updated October 2020 guidelines,
ACOG/SMFM endorsed NIPT
screening for all pregnancies.¹

HIGHER DETECTION RATES

LOWER FALSE-POSITIVE RATES



NIPT data from a meta-analysis of the performance of NIPT screening for aneuploidies. Thirty-five studies conducted from January 2011 through December 2016 were included. The meta-analysis included peer-reviewed studies reporting on clinical validation or implementation of NIPT aneuploidy screening, in which data on pregnancy outcome were provided for >85% of the study population. These studies reported NIPT results in relation to fetal karyotype from invasive testing or clinical outcomes.⁵

*False-positive rate shown is a combined rate for trisomies 21, 18, and 13.

Serum screening data from a prospective validation study screening for trisomies 21, 18, and 13 in 108,982 singleton pregnancies undergoing routine care in 3 hospitals. Subjects were screened using a combination of maternal age, fetal nuchal translucency, fetal heart rate, serum-free β -human chorionic gonadotropin, and pregnancy-associated plasma protein-A between 11 weeks 0 days and 13 weeks 6 days gestation. The detection rate and false-positive rate at estimated risk cut-offs from 1 in 2 to 1 in 1000 were determined. Rates shown are for risk cut-off of 1 in 100. The proportions of trisomies detected were compared to their expected values in different risk groups.⁸

ACCURATE

EARLY

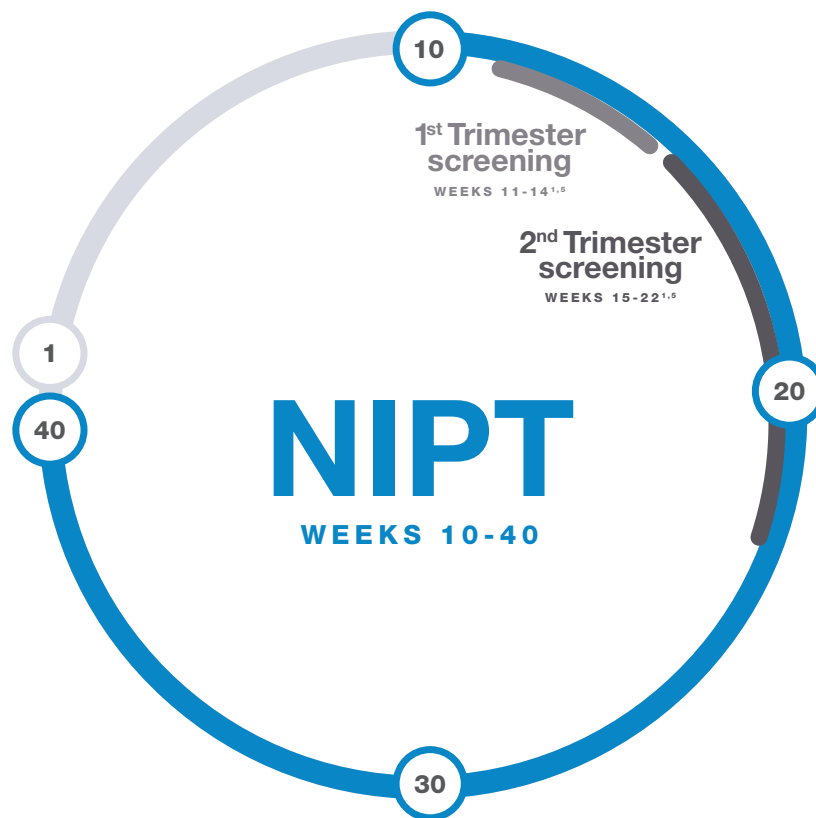
NONINVASIVE

FOR ALL PREGNANCIES



Insights as early as 10 weeks.

NIPT has the broadest screening window of any prenatal aneuploidy screening test^{1,5,7}



EARLY

NONINVASIVE

FOR ALL PREGNANCIES



Fewer invasive tests mean less maternal and fetal risk.

NIPT reduces the number of invasive confirmatory procedures performed in unaffected pregnancies ^{2,5,9-12}

NUMBER OF UNNECESSARY INVASIVE PROCEDURES FOR T21, T18, AND T13 OUT OF 1,000 PREGNANCIES

NIPT

False-positive rate: 0.13%⁵

~ 1

UNNECESSARY INVASIVE PROCEDURE



Conventional screening

False-positive rate: 4%⁸

40

UNNECESSARY INVASIVE PROCEDURES



Figures shown derived for a hypothetical population of 1000 pregnant women who would receive a false-positive result with each respective test, necessitating confirmatory diagnostic testing.

NONINVASIVE

FOR ALL PREGNANCIES



ACOG/SMFM endorse NIPT **for** **all pregnancies**¹

Cell-free DNA [NIPT] is the most sensitive and specific screening test for the common fetal aneuploidies (trisomies 21, 13, and 18) and can be performed at any time after 9-10 weeks of gestation.¹

—ACOG/SMFM clinical management guidelines for obstetricians and gynecologists

**OFFER NIPT TO ALL OF YOUR
EXPECTING PATIENTS
REGARDLESS OF AGE OR RISK¹**

Society guidelines endorse NIPT for all

“NIPT is the most accurate screening test for the common autosomal aneuploidies in unselected singleton populations and those at known increased probability.”

—International Society for Prenatal Diagnosis⁶

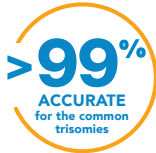
The systematic evidence review “demonstrated consistently superior performance of NIP[T]” and showed that NIPT outperforms other aneuploidy screening options “in all parameters and across all studies in general-risk populations” of singleton pregnancies.

—American College of Medical Genetics and Genomics (ACMG)⁷



IT'S TIME FOR NIPT FOR ALL

Endorsed by ACOG/SMFM for all pregnancies¹



Screen for the presence of T21, T18, and T13 with the most accurate prenatal aneuploidy screening test available^{1,2,5,6,9}



Gain insights into prenatal genetic health risks as early as week 10¹



Reduce the number of invasive procedures in unaffected pregnancies^{2,5,9-11}

Limitations of Test

NIPT (noninvasive prenatal testing) based on cell-free DNA analysis from maternal blood is a screening test; it is not diagnostic. False-positive and false-negative results do occur. Test results must not be used as the sole basis for diagnosis. Further confirmatory testing is necessary prior to making any irreversible pregnancy decision. A negative result does not eliminate the possibility that the pregnancy has a chromosomal or subchromosomal abnormality. This test does not screen for birth defects such as open neural tube defects, or other conditions, such as autism. Some NIPT tests do not screen for polyploidy (eg, triploidy) or single-gene disorders. There is a small possibility that the test results might not reflect the chromosomal status of the fetus, but may instead reflect chromosomal changes in the placenta (ie, confined placental mosaicism [CPM]) or in the mother that may or may not have clinical significance.

References: 1. Rose NC, Kaimal AJ, Dugoff L, Norton ME; American College of Obstetricians and Gynecologists' Committee on Practice Bulletins—Obstetrics; Committee on Genetics; Society for Maternal-Fetal Medicine. Screening for fetal chromosomal abnormalities. *Obstet Gynecol.* 2020;136(4). doi: 10.1097/AOG.0000000000004084. 2. Bianchi DW, Parker RL, Wentworth J, et al; for CARE Study Group. DNA sequencing versus standard prenatal aneuploidy screening. *N Engl J Med.* 2014;370(9):799–808. 3. Farrell RM, Mercer MB, Agatisa PK, Smith MB, Philipson E. It's more than a blood test: patients' perspectives on noninvasive prenatal testing. *J Clin Med.* 2014;3(2):614–631. 4. Lewis C, Hill M, Chitty LS. Women's experiences and preferences for service delivery of non-invasive prenatal testing for aneuploidy in a public health setting: a mixed methods study. *PLoS One.* 2016;11(4):e0153147. doi:10.1371/journal.pone.0153147. 5. Gil MM, Accurti V, Santacruz B, Plana MN, Nicolaides KH. Analysis of cell-free DNA in maternal blood in screening for aneuploidies: updated meta-analysis. *Ultrasound Obstet Gynecol.* 2017;50:302–314. 6. Hui L, Ellis K, Mayen D, Pertile M, D., Reimers R, Sun L, Vermeesch J, Vora N, L. and Chitty L. S. (2023), Position statement from the International Society for Prenatal Diagnosis on the use of non-invasive prenatal testing for the detection of fetal chromosomal conditions in singleton pregnancies. *Prenatal Diagnosis*, 43: 814–828. <https://doi.org/10.1002/pd.6357>. 7. Noninvasive prenatal screening (NIPS) for fetal chromosome abnormalities in a general-risk population: An evidence-based clinical guideline of the American College of Medical Genetics and Genomics (ACMG). *Genet Med.* 2023 Feb;25(2):100336. doi: 10.1016/j.jgm.2022.11.004. Epub 2022 Dec 16. PMID: 36524989. 8. Santorum M, Wright D, Syngelaki A, Karagiorgi N, Nicolaides KH. Accuracy of first-trimester combined test in screening for trisomies 21, 18 and 13. *Ultrasound Obstet Gynecol.* 2017;49(6):714–720. 9. Chudova DI, Sehner AJ, Bianchi DW. Copy-number variation and false positive prenatal screening results. *N Engl J Med.* 2016;375(1):97–98. 10. Platt LD, Janicki MB, Prosen T, et al. Impact of noninvasive prenatal testing in regionally dispersed medical centers in the United States. *Am J Obstet Gynecol.* 2014;211(4):368.e1–368.e7. 11. Larion S, Warsof SL, Romary L, Mlynarczyk M, Peleg D, Abuhamad AZ. Association of combined first-trimester screen and noninvasive prenatal testing on diagnostic procedures. *Obstet Gynecol.* 2014;123(6):1303–1310. 12. 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.

This material is intended for healthcare professional audiences only.