Now endorsed by ACOG and SMFM for all pregnancies regardless of age or risk[1]

IT'S TIME FOR NIPT FOR ALL

GET ACCURATE PRENATAL INSIGHTS AS EARLY AS WEEK 10.[1]

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

ACCURATE

EARLY

NONINVASIVE

FOR ALL PREGNANCIES

The accuracy of NIPT can reduce patient anxiety about false positives[2-4]

>99% ACCURATE

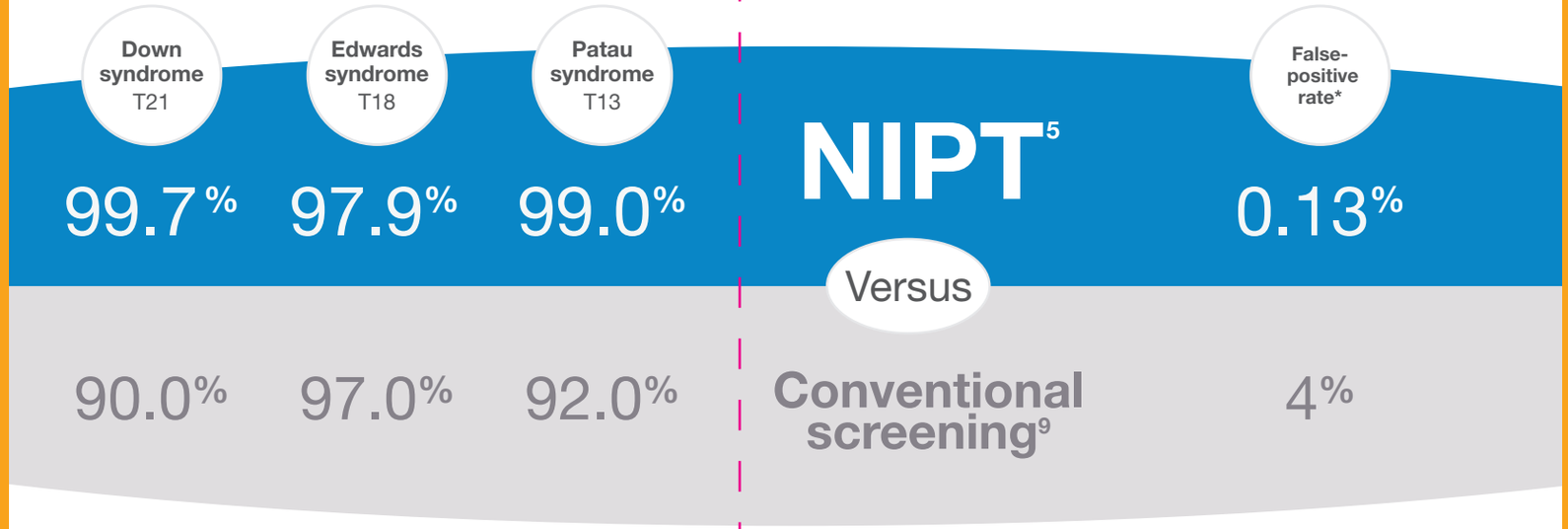
Accurate insights. Recommended for all.[1]

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

NIPT is a more accurate prenatal aneuploidy screening option than conventional prenatal serum screening, and is available for all pregnant women[1,6-8]

HIGHER DETECTION RATES

LOWER FALSE-POSITIVE RATES



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

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]

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 ß-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.[9]

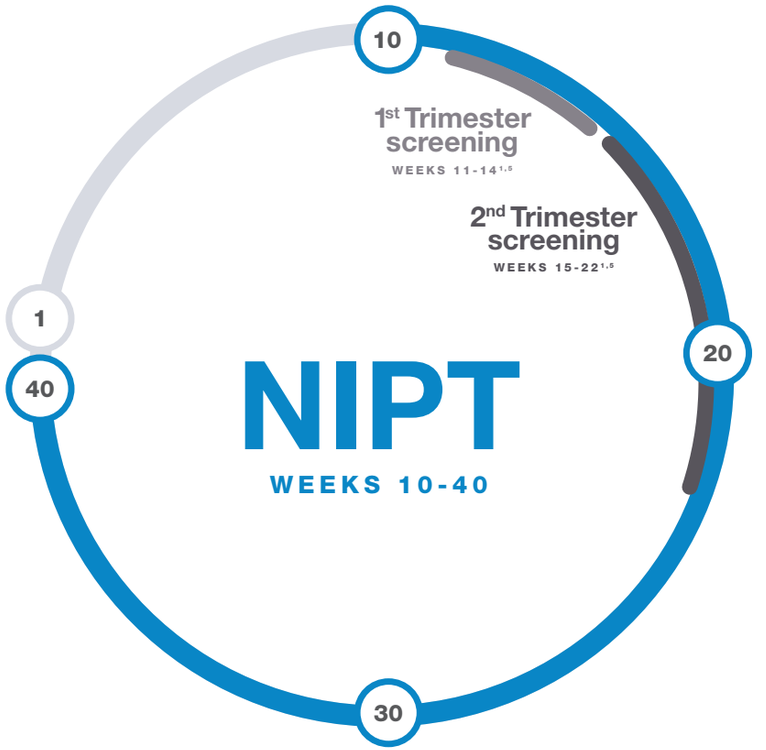
ACCURATE
EARLY
NONINVASIVE
FOR ALL PREGNANCIES

NIPT can be used at any time in pregnancy, beginning as early as week 10[1,5,8]

WEEK 10

Insights earlier than ever before.

NIPT has the broadest screening window of any prenatal aneuploidy screening test[1,5,8]



EARLY

NONINVASIVE

FOR ALL PREGNANCIES

The high sensitivity and specificity of NIPT enable a reduction in confirmatory invasive procedures, their sequelae, and costs[2,5,7,10-12]

Fewer invasive tests mean less maternal and fetal risk.

NIPT reduces the number of invasive confirmatory procedures performed in unaffected pregnancies[2,5,7,10-11]

NUMBER OF UNNECESSARY INVASIVE PROCEDURES FOR T21, T18, AND T13 OUT OF 1000 PREGNANCIES

NIPT

False-positive rate: 0.13%[5]

~1

UNNECESSARY INVASIVE PROCEDURE

Conventional screening

False-positive rate: 4%[9]

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

Supported by society guidelines[1,6,8]

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 MOTHERS REGARDLESS OF AGE OR RISK[1]

Society guidelines endorse NIPT for all

"There is now increasing evidence to show that the testing can also be applied to women with average risk... The following protocol options are currently considered appropriate: cfDNA screening as a primary test offered to all pregnant women."

—International Society for Prenatal Diagnosis (ISPD)[6]

"Clinical validation strongly suggested that NIPS can replace conventional screening for Patau, Edwards, and Down syndromes. Objective measures of clinical utility support this. Test metrics support NIPS across the maternal age spectrum."

—American College of Medical Genetics and Genomics (ACMG)[8]

cfDNA=cell-free DNA; NIPS=noninvasive prenatal screening.

FOR ALL PREGNANCIES

IT'S TIME FOR NIPT FOR ALL

Endorsed by ACOG/SMFM for all pregnancies[1]

Screen for the presence of T21, T18, and T13 with the most accurate prenatal aneuploidy screening test available[1,2,5-7]

Gain insights into prenatal genetic health risks as early as week 10[1]

Reduce the number of invasive procedures in unaffected pregnancies[2,5,7,10,11]

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.

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