

**NEW TEST**

NOTIFICATION DATE: February 6, 2018

EFFECTIVE DATE: February 13, 2018

**CELL-FREE DNA PRENATAL SCREEN, AUTOSOMAL TRISOMY AND  
SEX CHROMOSOME ANEUPLOIDY**

Test ID: NIPST

**USEFUL FOR:**

Noninvasive screening for aneuploidies of chromosomes 13, 18, 21, and sex chromosomes X and Y in pregnancies

**Important:** Mayo Medical Laboratories is licensed to perform NIPS testing only for clients located in the North and South American continents. If you reside outside of this authorized region, contact an alternative provider to perform similar testing.

**METHOD:** Whole Genome Sequencing of Plasma Cell-Free DNA

**TESTING ALGORITHM:**

This test is **only** available to clients in North and South America.

When this test is ordered, additional statistical analysis to determine the percentage of fetal DNA present is always performed.

The following algorithms are available in Special Instructions:

- Prenatal Aneuploidy Screening and Diagnostic Testing Options
- High-Risk Pregnancy Based on Abnormal Fetal Malformations: Laboratory Testing Algorithm

**REFERENCE VALUES:** An interpretive report will be provided.

**SPECIMEN REQUIREMENTS:**

**The following information is required** with each specimen:

1. Reason for referral
2. Maternal age
3. Number of fetuses
4. Gestation age (weeks and days)
5. Method of determining gestational age
6. Maternal height (inches)
7. Maternal weight (pounds)

The laboratory will not reject testing if this information is not provided, but appropriate testing and interpretation may be delayed or compromised.

**Supplies:** Streck Black/Tan Top Tube Kit (T715)

**Specimen Volume:** Two 10-mL Streck Cell-Free DNA blood collection tubes

**Additional Information:**

1. Specimens received from patients who are considered "low risk" will not be rejected but insurance may not cover testing.
2. Prior Authorization is available for this test. **Submit the required form with the specimen.**

**Forms**

1. New York Clients-Informed consent is required. Please document on the request form or electronic order that a copy is on file. An Informed Consent for Genetic Testing (T576) is available in Special Instructions.
2. Cell-Free DNA Prenatal Screen Prior Authorization Ordering Instructions in Special Instructions.
3. Cell-Free DNA Prenatal Screen Patient Information in Special Instructions.
4. Cell-Free DNA Prenatal Screen Patient Information FAQ in Special Instructions.

**SPECIMEN STABILITY INFORMATION:**

Specimen Type	Temperature	Time	Tube
Whole Blood	Ambient (preferred)	7 days	Streck Black/Tan top
	Refrigerated	7 days	Streck Black/Tan top

**CAUTIONS:**

This screen is available for patients starting at 10-weeks gestation.

This test screens for aneuploidies of chromosomes 13, 18, 21, and the sex chromosomes (X, Y). If screening for only chromosomes 13, 18, and 21 is desired, order NIPS / Cell-Free DNA Prenatal Screen.

**CPT CODE:** 81420

**DAY(S) SET UP:** Samples processed Monday through Sunday. Results reported Monday through Friday 8am-5pm CT

**ANALYTIC TIME:** 7 days

QUESTIONS: Contact your Mayo Medical Laboratories' Regional Manager or Heather Flynn Gilmer/Michaela Erickson, MML Laboratory Technologist Resource Coordinator  
Telephone: 800-533-1710