

## **Prenatal Cell-Free DNA Screening v3.0 assay (aka NIPT or NIPS) – Test Update**

**Orderable:** PRENATAL CELL-FREE DNA SCREEN (13, 18, 21, X, Y) (+/- 22Q)  
[LAB1231602]

**Effective August 8<sup>th</sup>, 2024, the Molecular Diagnostics Laboratory will start offering the option to add 22q11.2 microdeletion screening in addition to the common aneuploidies [chromosomes 13 (Patau syndrome), 18 (Edwards syndrome), 21 (Down syndrome), the sex chromosomes (i.e., Monosomy X, XXX, XXY)] as part of the Prenatal Cell-Free DNA Screening v3.0 assay. This cell-free fetal DNA screening can be ordered for singleton, twin gestations, and egg donor pregnancies.**

### **Explanation:**

#### **Epic ordering:**

- Test name: “Prenatal Cell-Free DNA Screen (13, 18, 21, X, Y) (+/- 22Q)”
- If desired, add the 22q11.2 microdeletion by selecting this on order questionnaire.
- If 22q microdeletion is not desired, Epic will trigger the “NIPT (13, 18, 21, X, Y)” test.
- If this test was previously part of an order set, favorite or preference list, it will be removed at go-live and will need to be manually re-added by the provider.
- Specimen collection and handling remain the same.
- Turnaround time remains the same.

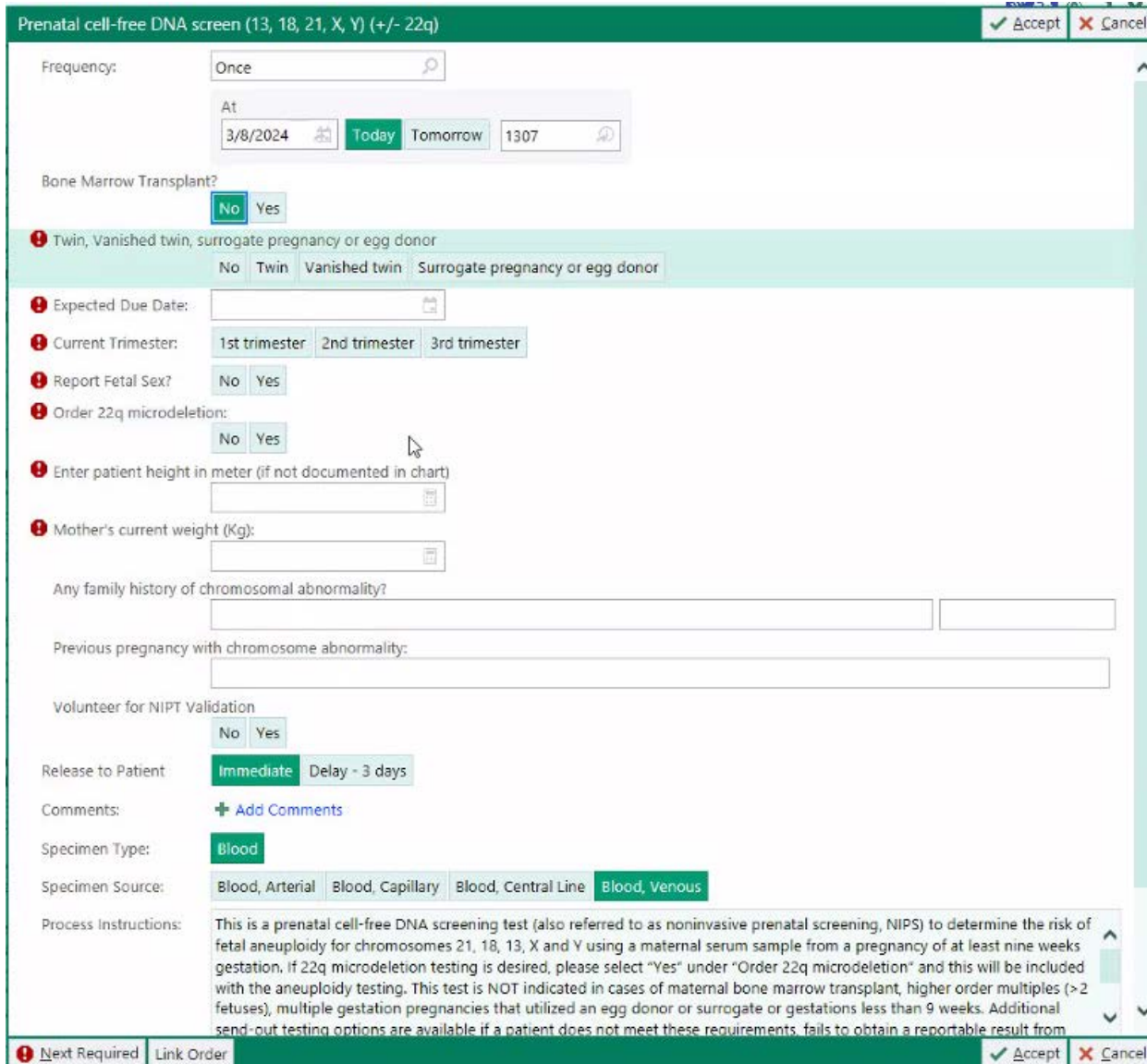
#### **Assay limitations:**

- Pregnancies must be at least nine weeks gestation.
- Testing cannot be performed for twin pregnancies utilizing an egg donor or surrogate.
- Not validated for higher order multiples (i.e. triplets, etc.).
- Patients who are bone marrow transplant recipients need alternate test.
- Minimum fetal fraction (CFE) of 2.8% for singleton and twin pregnancies.

### Changes to the report:

- If the 22q11.2 microdeletion option is selected, the report will also include results for this condition.

### Example Order Screen with Required Questions Indicated with Red Exclamation Point



**Prenatal cell-free DNA screen (13, 18, 21, X, Y) (+/- 22q)** Accept Cancel

Frequency:

At:  Today Tomorrow

Bone Marrow Transplant?  No  Yes

**!** Twin, Vanished twin, surrogate pregnancy or egg donor  
 No  Twin  Vanished twin  Surrogate pregnancy or egg donor

**!** Expected Due Date:

**!** Current Trimester:  1st trimester  2nd trimester  3rd trimester

**!** Report Fetal Sex?  No  Yes

**!** Order 22q microdeletion:  No  Yes

**!** Enter patient height in meter (if not documented in chart):

**!** Mother's current weight (Kg):

Any family history of chromosomal abnormality:

Previous pregnancy with chromosome abnormality:

Volunteer for NIPT Validation  No  Yes

Release to Patient:  Immediate  Delay - 3 days

Comments: [+ Add Comments](#)

Specimen Type:  Blood

Specimen Source:  Blood, Arterial  Blood, Capillary  Blood, Central Line  Blood, Venous

Process Instructions: This is a prenatal cell-free DNA screening test (also referred to as noninvasive prenatal screening, NIPS) to determine the risk of fetal aneuploidy for chromosomes 21, 18, 13, X and Y using a maternal serum sample from a pregnancy of at least nine weeks gestation. If 22q microdeletion testing is desired, please select "Yes" under "Order 22q microdeletion" and this will be included with the aneuploidy testing. This test is NOT indicated in cases of maternal bone marrow transplant, higher order multiples (>2 fetuses), multiple gestation pregnancies that utilized an egg donor or surrogate or gestations less than 9 weeks. Additional send-out testing options are available if a patient does not meet these requirements. fails to obtain a reportable result from

**!** Next Required [Link Order](#) Accept Cancel

For questions, please contact Pathology Client Services at (804) 828-7284 or the Molecular Diagnostics Laboratory at (804) 828-9564.