Notification Date: July 30th, 2024
Effective Date: August 8th, 2024

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 8th, 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.

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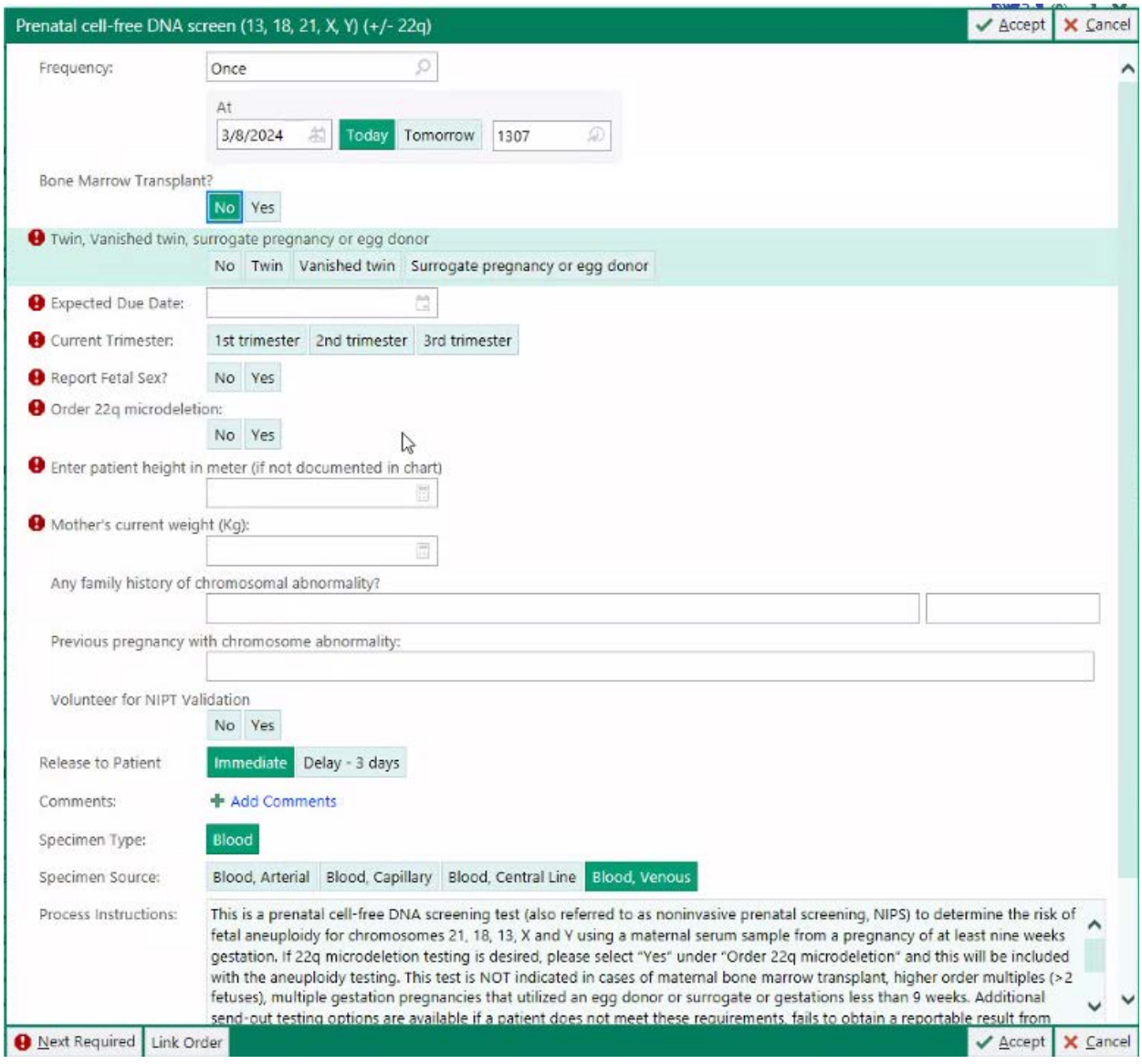
Changes to the report:

- 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



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