

Informed Consent: Common Early Prenatal Screens

These tests are the most common *screenings* currently available to evaluate risk of a fetus that has Down Syndrome (Trisomy 21), Trisomy 13, Trisomy 18, Turner's Syndrome or Neural Tube Defects. Screening tests are not diagnostic so each of the tests have percentages of false positives and false negatives.

These tests are offered to you but are not a required test. Since they are screening tests, it is important to consider what you would do with the information – nothing vs. more invasive testing. Because these are screenings, some tests will come back with false positives (when the test gives you a higher ratio that your baby has a particular condition) and sometimes there are false negatives (when the test inaccurately reports that your baby has a very low risk of a particular condition). Consider all of the risks and benefits in your decision to have these tests performed, having the knowledge of a possible condition can lead to a lot of emotions and decisions. When you're making your decision, consider what you would do if you did get a positive screen.

*Sensitivity: The higher the sensitivity, the fewer are the *false negatives*.

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| A. Combined & Integrated Screens | } Referred Out of Office |
| B. Complete genetic consultation | |
| C. Quad Screen | } In Office |
| D. MaterniT21 | |

A. Combined & Integrated Screen (11 – 12w6d)

- What:** An ultrasound that measures nuchal translucency, a portion of the neck, and a blood draw during the first trimester. The integrated screen adds a 15-22 week blood draw which increases the accuracy of the test, you can elect to forego this blood draw.
- Purpose:** Screening for Trisomy 21, Trisomy 13, Trisomy 18, and Turner's Syndrome. Sensitivity is 85-91% and a false positive rate of 5%. The false positive rate decreases to 1% with the integrated screen.
- Benefits:** Test is performed in early pregnancy and the results are given soon after the test is performed. Minimally invasive.
- Risks:** Risks associated with a blood draw. Risk of a false positive is high, comparatively. Unknown risks associated with ultrasound. This test needs a referral by your midwife to an outside facility in order to be performed.

B. Quad Screen (15 – 20w)

- What:** A blood draw that evaluates levels of AFP, hCG, UE3, and Inhibin A and combines maternal information of age, weight, and family history to give a risk ratio.
- Purpose:** Screening for Down Syndrome, Trisomy 18, and neural tube defects. Sensitivity of 70% with a false positive rate of 5%.
- Benefits:** Can be done in the office, no outside appointments necessary. No additional ultrasounds.
- Risks:** Risks associated with a blood draw. Screens for fewer disorders than both the Combined Screen. Is only performed in the second trimester. Risk of a false positive is high, comparatively and is even higher if data is not accurate.



D. MaterniT21 Plus (10+ weeks)

What: A maternal blood draw that evaluates "fetal DNA"

Purpose: Screening for Down Syndrome. It is reported to be 99.4% accurate when mothers have particular risk factors.

Benefits: High level of accuracy, performed early in gestation.

Risks: This is a newer test so full trials have not been accomplished. There is evidence that suggests when mothers don't have risk factors, it is not as accurate because all of the trials have been done on with women risk factors. This test can be performed in the office.

E. Complete genetic consultation

What: A complete genetic consultation is done in a maternal fetal medicine specialty clinic and usually includes a perinatologists evaluating a family's risk of Spinal Muscular Atrophy, Cystic Fibrosis, Fragile X Syndrome as well as evaluating identifiable risk factors for a particular family.

☐ I would not like any prenatal screening

☐ I would like to have the Combined &/or Integrated Screen

☐ I would like to have the Quad Screen

☐ I would like to have the MaterniT21 Plus Screen

☐ I would like to have a complete genetic consultation

By signing below, I accept full responsibility for my decision.

Client's Signature

Printed Name

Date

Partner/Spouse Signature

Midwife's Signature