GALEN
MEDICAL GROUP

Prenatal Screening Consent Form

The American College of OBGYN (ACOG) recommends "prenatal screening or diagnostic testing should be discussed and offered to all women early in pregnancy." The incidence of chromosome abnormalities increases as a woman ages but can affect *any* woman regardless of age and is not related to race or ethnicity.

There are some women at higher risk of having a baby with chromosomal abnormalities. This includes:

- Maternal age 35 or older at the time of delivery
- A prior pregnancy with a chromosomal abnormality
- Ultrasound markers or screening tests reporting increased risk
- Either parent with a chromosomal abnormality (balanced Robertsonian translocation)

Down syndrome is the most common chromosomal abnormality, with ~6,000 affected infants born in the U.S. each year. Down syndrome causes mental retardation and is associated with a variety of birth defects. Trisomy 18 is another chromosomal disorder that causes severe mental retardation, various birth defects, and is always fatal, causing still birth or death in infancy. Neural tube defects affect a baby's spinal cord or brain. This can cause leg weakness or paralysis, up to incomplete brain development. A neural tube defect that occurs along the spine is known as spina bifida.

There are a wide variety of screening test options for the most common prenatal abnormalities, each offering varying levels of information and accuracy. No one screening test is superior to other screening tests in all characteristics. Each test has relative advantages and disadvantages, with differing benefits, risks, and limitations.

It is important to remember that a "positive" result does not mean that the baby a problem. Likewise, a "negative" result does not guarantee that a baby has no problems. If a screening test shows increased risk, further evaluation with diagnostic testing would be discussed and offered.

It is also important to understand that every pregnancy has some risk (3-5%) of the kinds of problems that cannot be diagnosed during pregnancy, such as autism, mental retardation and some types of physical defects or genetic diseases.

Prenatal Testing Options

Test	Weeks Performed	Down Syndrome Detection Rate	Trisomy 18 Detection Rate	Neural Tube Defect Detection Rate	False Positive Screen Rate	Risk to Baby
Ultrasound	18-20	~70%	>95%	>90%	-	None
Cell free DNA	After 10	99%	98%	Unable to detect	0.5%	None
Quad Screen	15-22	81%	80%	80%	5%	None
Chorionic Villus Sampling	10-13	99%	99%	Unable to detect	Near 0%	1% miscarriage risk
Amniocentesis	After 15	99%	99%	Above 90%	Near 0%	0.5% miscarriage risk

Cell Free DNA (also called Non-Invasive Prenatal Screening, i.e. NIPS) – Uses a maternal blood sample after 10 weeks of pregnancy. Evaluates risk of Down syndrome, trisomy 18, trisomy 13 and sex chromosome abnormalities. Does not screen for neural tube defects, therefore an additional blood test (AFP) may be done between 15-22 weeks to screen for spina bifida. The likelihood of a "false positive" result is dependent on baseline risk of the individual related to age and other factors. In high risk patients, a positive screen is a "true positive" 83% of the time. In lower risk patients, a positive screen is a "true positive" 33% of the time. *Generally not covered by insurance, unless in a high risk group.*

Quadruple Screen (Quad Screen) – Offers simplicity of a single maternal blood sample between 15-22 weeks to screen for Down syndrome, trisomy 18 and neural tube defects.

Chorionic Villus Sampling (CVS) – Is an invasive test involving a procedure to remove a small sample of tissue from the placenta between 10-13 weeks of pregnancy. It can detect 98% of all chromosomal and genetic disorders. It does not screen for neural tube defects and other birth defects. As this involves an invasive procedure, there is a ~1% risk of miscarriage from the procedure itself.

Amniocentesis – Is an invasive procedure that involves removing a small sample of amniotic fluid from the uterus. It is performed any time after 15 weeks of pregnancy and tests for the same chromosomal and genetic disorders as CVS with a 99% detection rate. In addition, it can screen for neural tube defects. The risk of miscarriage is ~0.5%.

Based on the information above, I would like the following testing:

_____ No screening

_____ Cell free DNA screening

_____ Quadruple screening

----- Chorionic villus sampling

----- Amniocentesis

Cost of testing is dependent on your insurance carrier and deductible. (Please initial) _____

My signature below indicates I understand the above and have had all questions answered to my satisfaction.

_____ _____

Patient Signature Date

5/25/2017