Caring For Women
Obstetrics & Gynecology

Prenatal Testing Consent Form

Congratulations on the news of your pregnancy! The providers at CFW are excited to partner with you to ensure the best outcome for you and your baby. We offer several choices for screening of birth defects. **Screening is simply an option**. **You may choose not to do any screening**. We encourage you to think about what you would do with the information gained by testing.

It is important to know that there are many genetic problems a baby can have. Routine screening is very limited as to what conditions are identified. The main conditions for which screening is available are:

1) Trisomy 21 (Downs Syndrome) is the presence of an extra piece of chromosome 21. This defect differs widely in the way it is expressed. Some babies are severely affected, while others are only mildly affected. Occasionally, these babies have cardiac defects which necessitate their delivery in a different hospital.
2) Trisomy 18 is the presence of an extra piece of the 18th chromosome. These babies have multiple defects and usually cannot live outside the uterus for more than a few months after delivery.
3) Trisomy 13 is the presence of an extra piece of the 13th chromosome. These babies have multiple defects and usually cannot live outside the uterus for more than a few months after delivery
4) Neural tube defects, such as spina bifida, occur when the cells that form the spine and the spinal cord don't fuse together properly as an embryo forms. The problem may be extremely mild or severe.

Please initial which testing you desire:

Invasive Tests-These are ***diagnostic*** tests. They test for Trisomies and other indicated genetic defects

_____ 1. Chorionic Villus Sampling: This is a test taking cells from the placenta performed between 10-12 weeks by the high risk OB specialist. There is a risk of miscarriage in this test which is quoted at about 1:200. Other risks include infection and bruising. The sensitivity is 99%.

_____ 2. Amniocentesis: This is a test taking fluid from around the baby performed at 13-20 weeks. There are risks with this procedure including miscarriage, infection, and injury to the baby, Rh sensitization and leaking amniotic fluid. The sensitivity is 99%.

_____ I ***decline*** invasive testing.

Non-Invasive Tests for Trisomies** - These are ***screening tests. You may choose 1, 2, or 3. MSAFP is a separate test and can be added to the genetic testing.

_____ 1. *Quad screen* – This is a blood test performed between 16 and 21 weeks which screens for genetic defects but is not as predictive as the Sequential Screen and Genetic testing. This test includes the MSAFP. This test will detect about 75 -80% of trisomy 21 and 18 and have a higher false positive rate of around 5%. Open spina bifida is detected at 80% with a 1-3% false positive rate.

_____ 2. *Sequential Screen* – Includes an ultrasound and a finger stick blood test at 12 weeks and a blood draw at 15-21 weeks. Trisomy 21 and 18 are detected at 90-92.3%, with a 3.5% false positive rate. Open spina bifida is detected at 80% with a 1-3% false positive rate.

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_____ 3. *Genetic testing* – **This is recommended for women over 35, or couples with a family history of genetic defects or an abnormal sono**. This is a blood test which counts the chromosomes and is completed after 10 weeks. Trisomies are detected at 99% for trisomy 21 and 18 and 80% for trisomy 13. This test has a false positive rate of 0.1%.

_____ I would like this test without gender

_____ I would like this test with gender

_____***MSAFP*** is a blood test done between 16-20 weeks. This test screens for neural tube defects like spina bifida. This test has an 80% detection rate with 1-3% false positive results.

_____***I Decline*** serum testing for birth defects on my baby.

A 20 week sonogram will be completed on your baby. This will screen for certain birth defects but has a higher probability of false positive and false negatives than the screening or diagnostic testing.

_____For women over 35, with a BMI over 30, diabetes or in vitro fertilization, CFW recommends that you have a special sonogram for the baby's heart at 24 weeks with a Maternal Fetal Specialist.

Please note that insurance coverage for these tests are dependent upon your own individual insurance policy and may or may not be a covered benefit. If not covered by your insurance, the test bill will be pt responsibility.

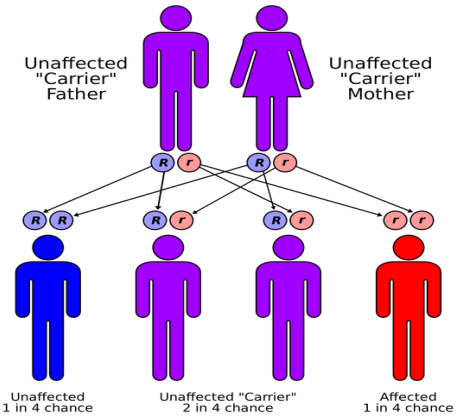
Printed Name of Patient: _____ DOB: _____

Signature of Patient: _____ Date: _____

Signature of Physician: _____ Date: _____

What is Carrier Screening?
Carrier screening is a **non-invasive** type of genetic test that determines if a person is a carrier for a specific recessive condition. Carriers typically do not have the condition, but screening can be helpful to couples to determine the chances of their child inheriting a recessive condition. Carrier screening and counseling ideally should be performed before pregnancy because this enables couples to learn about their reproductive risk and consider the most complete range of reproductive options (ACOG, 2017)

Can anyone be a carrier?
Yes, each person has two copies of a gene, one inherited from each parent. If a person has one normal gene and one abnormal gene, that person is a carrier of the disease and therefore, does not have symptoms of the disease, but may be able to transmit that gene to an offspring. However, an offspring can inherit the disease if both parents are carriers of the same abnormal gene. In this scenario, the risk of the disease would be 25% (1 out of 4). The risk of carrier state would be 50% (2 out of 4) and the chances of completely normal genes would be 25%.



Your ethnic background also significantly contributes to whether or not you are a carrier of a specific genetic disorder. For example, cystic fibrosis is more common in people of Caucasian and Ashkenazi Jewish descent. Sickle cell disease is more common in people of African descent and Tay-Sachs disease, is more likely to occur among people of Ashkenazi (eastern and central European) Jewish or French Canadian ancestry. It is important to note, however, that these disorders can occur in any ethnic group.

If someone in your family has a genetic condition, then your risk of being a carrier is increased above what your risk is based on ethnic background.

What if my test is positive?
A positive result tells you with greater than 99% certainty that you are a carrier of a genetic disorder, and you could be at risk of having an affected child **if** your partner is also a carrier of that genetic disorder.

If you test positive, you may wish to consider genetic carrier screening for your partner, or pursue genetic counseling. If your partner is confirmed to also be a carrier and you are already pregnant, then certain prenatal testing can be performed to find out whether your baby has inherited the genetic disorder.

Carrier screening test only has to be done once in a lifetime and is different from the non-invasive prenatal testing (NIPT) which looks for trisomy markers and neural tube defects. Ask your healthcare provider about adding carrier screening to your NIPT (if desired) at no additional cost.

At Caring for Women, we recommend and offer to all women who are pregnant or considering pregnancy, at a minimum, screening for these conditions, as recommended by the American College of Obstetricians and Gynecologists (ACOG):

- **Cystic Fibrosis** –This disorder affects many of the important functions of the digestive and respiratory systems. Symptoms range from mild to severe. People with this disorder have a low life expectancy
- **Spinal Muscular Atrophy** – a disorder that affects mainly the musculoskeletal and neurological system. It is the number one genetic cause of deaths for infants. SMA affects approximately 1 in 11,000 babies, and about 1 in every 50 Americans is a genetic carrier. SMA can affect any race or gender.

These other recommended carrier screening tests may be ordered depending on your family history and/or ethnic background. Please speak to your provider if you would like to know more or have these included.

- **Hemoglobinopathy –** an abnormality in the genetic makeup of the hemoglobin (a vital component of the red blood cells). Disorders in this category can affect quality of life. An example is sickle cell disease.
- **Tay Sachs -** this disease progressively destroys nerve cells and significantly affects quality of life. It is most common in people of Eastern or Central European Jewish, French Canadian, and Cajun descent.
- **Fragile X syndrome –** This condition causes a range of developmental problems including learning disabilities and cognitive impairment. Usually, males are more severely affected by this disorder than females. Affected individuals usually have delayed development of speech and language by age 2. Testing is recommended for women with a family history of fragile X-related disorders or intellectual disability suggestive of fragile X syndrome. Also, women with unexplained ovarian insufficiency/failure or an elevated follicle-stimulating hormone level before age 40 years

Note:
Like most medical tests, there are limitations to these tests because not all mutations of some genes are known. A negative test does not guarantee that your baby is not affected. Prenatal Carrier screening does not replace newborn screening, nor does newborn screening replace the potential value of prenatal carrier screening.

Informed Consent:

1. I understand that the decision to be tested for carrier status is completely mine.
2. I understand that the test does not detect all genetic disorders.
3. I understand that if both parents are carriers, additional testing can be done in order to know whether or not the baby will have a genetic disorder.

I have read and understand the information presented to me regarding Carrier testing.

_____ I do ***not*** want carrier testing

_____ I want carrier testing as recommended by my healthcare professional, tailored to my needs.

Comments_____

Printed Name of Patient: _____ DOB: _____

Signature of Patient: _____ Date: _____

Signature of Witness: _____ Date: _____

Caring For Women
Obstetrics & Gynecology

Pregnancy Blood/Urine Panel
HIV Blood Test Consent

What is HIV? The Human Immunodeficiency Virus (HIV) is a virus that is the cause of AIDS. AIDS is a name given to a group of serious diseases that result in the suppression of the body's immune system by the virus now commonly known as HIV.

What is the test and what does it tell you? A sample of your blood will be tested to see if it contains antibodies to HIV, which may indicate that infection has occurred. There are limitations to the accuracy of any chemical test and results are not 100% accurate. The test may be useful in clinical situations and may help you and your physician make decisions.

I voluntarily consent to be tested in order to detect whether or not I have had exposure to the human immunodeficiency virus (HIV) which is the causative agent of acquired immune deficiency syndrome (AIDS). I realize that I may refuse the test. I know that the test will be performed by drawing blood and using a substance to test the blood. I know that my test results are confidential under Texas law, and that unless I specify otherwise, the test result will be released to the physician who ordered the test, and to other persons only as required by law.

The opioid crisis has affected far too many people in our country, including pregnant women and newborns. The risk of stillbirth is increased 2-3 times for a woman who smokes (tobacco or marijuana), takes prescription pain medications, or uses illicit drugs during her pregnancy. A newborn of a woman using various medications or drugs may undergo severe withdrawal symptoms at birth. CFW is committed to providing the very best care for our pregnant patients and part of that commitment is ensuring we help any woman who may be using or misusing drugs or medications. We have instituted a policy of urine drug screening on every pregnant patient at the beginning of her pregnancy and then as indicated during her pregnancy. The goal of this is not to punish or embarrass anyone. It is to ensure our moms and their babies get the best quality care and assistance as early as possible if drug use is an issue. Please initial that you have read and understand this policy and consent to testing _____ or decline testing _____

What is included in the Pregnancy Blood and Urine Panel?

ABO & Rh	
Antibody Screen	Rubella Screen
CBC w/ Manual Diff	RPR (Syphilis)
Hepatitis B Surface Ag	Urine Culture & Sensitivity
HIV 1/2 SCREEN RFLX WB	Urine Toxicology Panel

I have read and understand the information presented to me regarding Pregnancy Panel and HIV testing and I:

_____ I do accept all testing listed above

_____ I do ***not*** want the following tests

Printed Name of Patient: _____ DOB: _____

Patient/ Guardian Signature: _____ Date: _____

Witness Signature: _____ Date: _____