UNITY

Clinic Consent For UNITY Screen

Everyone is at risk to have a baby with health concerns. There are a few common conditions that can occur even without a family history. **UNITY Screen determines my carrier status and my baby's risk for common disorders listed below. Screening for these conditions is recommended for all pregnant patients by the American College of Obstetricians and Gynecologists.**

CARRIER SCREENING

UNITY Screen will determine whether I am a carrier for cystic fibrosis, spinal muscular atrophy, alpha thalassemia, beta thalassemia, and sickle cell disease. If I am found to be a carrier, non-invasive prenatal screening (NIPT) will be performed for my pregnancy.

CONDITION	DESCRIPTION
CYSTIC FIBROSIS	Affects many organs such as the lungs, digestive system, and male fertility. It worsens over time and has no cure, although treatments to improve symptoms are available.
SPINAL MUSCULAR ATROPHY	Causes muscle weakness and wasting, decreased ability to breathe, and loss of motor skills. The most severe type begins in infancy with death often occurring before the age of two when untreated. Early treatment starting at birth may increase survival and improve symptoms.
ALPHA THALASSEMIA	Causes symptoms related to anemia such as tiredness, dizziness, and a rapid heartbeat. The most severe form is hemoglobin Bart syndrome, which is usually fatal during pregnancy or shortly after birth. Treatment started during pregnancy may increase the likelihood of survival.
BETA THALASSEMIA	Causes anemia, poor growth, and can affect the spleen, liver, heart, and bones if left untreated. People with beta thalassemia require life-long blood transfusions every 2-3 weeks.
SICKLE CELL DISEASE	Causes fatigue, pain, and other serious problems such as infections and stroke. Symptoms range from mild to severe and vary from person to person. Early diagnosis and treatment are important. The only cure is a bone marrow or stem cell transplant.

The following results are possible:

POSITIVE – Carriers are typically healthy, but at increased risk to have a child with that condition. If I screen positive for one or more of the conditions above **non-invasive prenatal screening will automatically be performed to determine the fetal risk for the condition.**

In rare cases results may reveal I have the condition or am at risk of developing symptoms in the future.

NEGATIVE – The risk of being a carrier and having a child with the conditions above is significantly reduced, but not eliminated. **Non-invasive prenatal screening will NOT be performed.**

CHROMOSOME ANEUPLOIDY SCREENING

UNITY Screen performs NIPT to assess the fetal risk for Down syndrome, trisomy 18, trisomy 13, and sex chromosome conditions. The risk for these conditions increases with maternal age; however **women of any age may have a pregnancy with these conditions.**

CONDITION	DESCRIPTION
DOWN SYNDROME (TRISOMY 21)	Individuals with Down syndrome are at risk for various medical health issues such as heart defects. Children with Down syndrome have developmental delays and varying degrees of intellectual disability.
TRISOMY 13 AND TRISOMY 18	These conditions are related to severe intellectual disability and multiple birth defects. Most infants with trisomy 18 and 13 do not survive past a year of age.
SEX CHROMOSOME CONDITIONS	Sex chromosome conditions may be related to learning difficulties and developmental delays, but are typically associated with normal intelligence. Some conditions are associated with birth defects and infertility. Some pregnancies may also be at increased risk for miscarriage.

POSSIBLE NON-INVASIVE PRENATAL SCREENING RESULTS

- **Low Fetal Risk** - the chance my baby is affected for the conditions screened is significantly reduced, but not zero. Low risk screening does not guarantee a normal pregnancy and healthy child.
- **High Fetal Risk** – my baby is at increased risk of being affected. Confirmatory testing via chorionic villus sampling or amniocentesis is strongly recommended. **No irreversible pregnancy decisions, such as pregnancy termination, should be considered based on UNITY™ results alone.**
- **No Result** - a result could not be obtained due to limited cell free fetal DNA or failed quality control metrics. Additional testing may be recommended.

- My results will be reviewed by my provider. Complimentary genetic counseling is also available through BillionToOne.

I acknowledge that I was offered screening for the conditions listed. My provider reviewed benefits, risks, and limitations of UNITY Screen . I was given an opportunity to ask questions and understand the information provided. If I decline, I understand I may be at risk to be a carrier and/or have a child affected with these conditions.

☐ I ELECT UNITY Screen CARRIER SCREENING

☐ I DECLINE UNITY Screen CARRIER SCREENING

☐ I ELECT UNITY Screen CHROMOSOME ANEUPLOIDY SCREENING

☐ I DECLINE UNITY Screen CHROMOSOME ANEUPLOIDY SCREENING

Patient Signature: _____

Patient Name: _____ **Date:** _____

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POWERED BY BillionToOne

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Clinic consent for UNITY Carrier Screen™ with Fragile X

Purpose of test

The purpose of this test is to determine your number of CGG repeats in the *FMR1* gene. The CGG repeats vary in size from person to person. The number of these repeats can impact how the gene works.

Certain numbers of CGG repeats are associated with fragile X syndrome and related disorders. Carrier screening for fragile X syndrome (FXS) is suggested by the American College of Obstetricians and Gynecologists (ACOG) for pregnant people with a family history of FXS or intellectual disability, and/or a history of primary ovarian insufficiency.

How is carrier screening for Fragile X performed?

UNITY carrier screen looks for changes within certain genes using a blood sample. This blood sample contains your DNA, or genetic material. Carrier screening can be performed on any person, male or female, and you do not have to be pregnant.

The results of this carrier screen only tells us information about your number of CGG repeats. It does not tell us about a pregnancy. This means the test cannot tell you if your baby has fragile X syndrome. It is recommended you discuss your carrier screening results with your healthcare provider or genetic counselor to understand possible implications for you and your children.

What We Are Screening For:

Typically, individuals have between 5-44 CGG repeats in the *FMR1* gene. Differences in the number of repeats can be associated with different implications for you or your children.

Possible Results and Implications:

5-44 repeats: *Negative Result* - This is considered a normal result, indicating no increased risk of FXS or related disorders.

45-54 repeats: *Intermediate Carrier* - Sometimes referred to as a "gray zone." It indicates a slight increase in the number of repeats, but is not known to cause FXAS or related disorders. However, these repeats can expand in each generation so your children could be premutation carriers.

55-200 repeats: *Premutation Carrier* - This Indicates an increased risk of having children with FXS and related disorders. These CGG repeats can expand to full mutations in your children. Premutation carriers can develop fragile X related conditions including a tremor/ataxia syndrome, often abbreviated as FXTAS, or primary ovarian insufficiency, or FXPOI. Because being a premutation carrier can sometimes affect your health, you should discuss this result with your healthcare provider.

>200 repeats: *Full Mutation Carrier* - This result typically indicates a full mutation of the gene, which is associated with FXS. The gene is predicted to stop working when in this repeat range and cause FXS in males. This range can also affect some females.

Acknowledgement of Risks and Benefits

Carrier screening for fragile X provides the opportunity to understand the potential to understand the potential risk of having children with FXS and related conditions. However, in some cases testing may reveal information about my risk for certain fragile X related conditions as well.

I acknowledge that I was offered screening for the conditions listed. My provider reviewed the benefits, risk, and limitations of UNITY Complete™. I was given the opportunity to ask questions and understand the information provided.

☐ I ELECT UNITY Complete™ ☐ I DECLINE UNITY Complete™

Patient signature: _____ **Date:** _____

Patient name: _____

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