SPECTRUM HEALTH

Patient Name
DOB
MRN
Physician
FIN

Consent
NONINVASIVE PRENATAL SCREENING (NIPS) FOR FETAL ANEUPLOIDY

INTRODUCTION:

I am being offered this screening to determine an estimated risk that my pregnancy has certain chromosome abnormalities. Fetal sex may also be reported in the results. This screen is available for women who are at least 10 weeks pregnant. NIPS cannot confirm a diagnosis or whether my baby has or does not have a chromosome abnormality. This screening is used to give an estimated risk for my pregnancy for these chromosome abnormalities:

- Trisomy 13 (Patau syndrome)
- Trisomy 21 (Down syndrome)
- Trisomy 18 (Edwards syndrome)
- Triploidy
- Certain sex chromosome aneuploidies

PROCEDURE:

GENETIC COUNSELING: I may ask for genetic counseling by a genetics professional before choosing to do NIPS. This counseling would include:

- Reviewing my family and medical histories
- Talking about the risks, benefits and limitations of all available testing choices

WHAT WILL HAPPEN:

- A blood sample will be taken from me and sent to Spectrum Health Molecular Diagnostics Laboratory.
- Only the specific test(s) that my healthcare provider orders will be run on my sample.
- Any unused part of my sample may be kept by the laboratory for quality control or validation reasons. My sample will not be used for research or other clinical testing unless I authorize it.

TEST RESULTS:

- Test results will be given ONLY to my doctor that ordered this screen _____ (name) or their agent. He/she would be responsible for telling me the results.
- A follow-up appointment for genetic counseling may be recommended.

WHAT NIPS RESULTS CAN TELL ME:

IF I AM AT LOW RISK:

- There is a decreased chance that my baby has the above listed chromosome abnormalities.
- This result does not guarantee normal chromosomes or a healthy baby (see LIMITATIONS section).

IF I AM AT HIGH RISK:

- There is an increased likelihood my baby has one of the chromosome abnormalities screened. This result does not guarantee that the baby has that abnormality. This result should not be used to make decisions about the pregnancy.
- If a sex chromosome abnormality is detected, the fetal sex will be reported in the results even if I did not wish to know.
- My healthcare provider will talk with me about the results and may recommend follow-up steps. These may include a referral to a genetic counselor or prenatal diagnostic testing (e.g., chorionic villus sampling (CVS), amniocentesis, testing the baby after delivery, etc.).

OVER ➔

DO NOT MARK BELOW THIS LINE — BARCODE ZONE — DO NOT MARK BELOW THIS LINE

* X 2 3 3 0 8 *

WHAT NIPS RESULTS CAN TELL ME: *(CONTINUED)*

IF THERE IS "NO CALL":

- A "no-call" result can happen for a variety of reasons. Women who do not get a result may be at unchanged or increased risk of carrying a baby with a chromosome abnormality.
- In some cases, I may be able to submit another sample at no additional charge. Submitting another sample does not always return a result.
- If my screen does not return a result, my healthcare provider will talk with me about the results and may recommend follow-up steps. These may include genetic counseling, comprehensive ultrasound, and diagnostic testing.

OTHER POSSIBILITIES:

- In rare cases, results may be unreportable due to a suspected maternal chromosome abnormality (such as Turner syndrome or triple X syndrome).
- In these cases, my healthcare provider will talk with me about the results and may recommend follow-up steps.

LIMITATIONS/RISKS:

- This screen will detect the majority of pregnancies in which the baby has one of the chromosomal abnormalities listed above. It cannot detect 100% of pregnancies with these conditions.
- About 1 - 2% of all pregnancies have confined placental mosaicism. This is a situation in which the placenta has cells with a chromosome abnormality, while the fetus has normal chromosomes, or the other way around. This means that there is a chance that the chromosomes in the fetus may not match the chromosomes in the DNA screened from the placenta.
- Only the chromosomal abnormalities listed above are screened for. This screen does look for abnormalities of untested chromosomes, other genetic disorders, birth defects or other complications in your fetus.
- This test was developed, and its performance characteristics determined by Spectrum Health Molecular Diagnostics Laboratory. It has not been cleared or approved by the U.S. Food and Drug Administration.
- Inaccurate test results or a failure to get test results may happen. This may be because one or more of the rare events listed below:
    - Courier/shipping delay
    - Sample mix-up
    - Laboratory failure or error
    - Biological factors such as but not limited to:
        - Sample contamination or degradation
        - Too little DNA from the fetus in the maternal blood sample
        - Mosaicism (a mixture of cells with normal and abnormal chromosomes) in the fetus, placenta or mother
        - Other genetic variants in the mother or fetus
        - An unrecognized twin pregnancy
    - Other situations beyond our control or unexpected problems that may happen.
- This screen cannot be done on:
    - Patients who are carrying multiple babies (e.g., twins, triplets, etc.)
    - A pregnancy with a vanishing twin
    - A pregnancy that used a donor egg or surrogate
    - A pregnancy in which the patient has had a bone marrow or solid organ transplant.

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NONINVASIVE PRENATAL SCREENING (NIPS) FOR FETAL ANEUPLOIDY *(CONTINUED)*

ALTERNATIVES:

- I do not have to be screened for chromosome abnormalities. The choice is up to me.
- There are other screens available during pregnancy besides NIPS. I can talk about these with my healthcare provider.
- If I want conclusive information about the fetal chromosomes, more invasive procedures are available (e.g., CVS, amniocentesis, etc.).

CONFIDENTIALITY:

Screening results will become part of my electronic medical record. My medical record will be kept confidential except when its use/disclosure is required/permitted by law, regulation or my authorization. My current/future insurance carriers will not have access to this information unless I authorize it to be released. If I want to authorize information to be shared with a specific person or company, I must do it in writing.

- I have read this form or it has been explained to me.
- All my questions about this form have been answered.

☐ I consent to noninvasive prenatal screening (NIPS) for fetal aneuploidy.

_____ ☐ AM ☐ PM _____ _____ Time Date Patient Signature

_____ ☐ AM ☐ PM _____ _____ **TIME** **DATE** Witness to Signature

If a patient is under 18 years of age or otherwise unable to consent, the following must be completed:

I,_____ , hereby certify that I am the _____ of the patient; that patient is unable to consent because patient is a minor, or because:

_____

_____ ☐ AM ☐ PM _____ _____ Time Date Signature of Parent, Legal Guardian, Patient Advocate or Next of Kin

_____ ☐ AM ☐ PM _____ _____ **TIME** **DATE** Witness to Signature

STATEMENT FOR INVASIVE PROCEDURES ONLY:

I have reviewed the patient consent form. The procedure for which the patient is consented conforms with the plan for this patient. I have discussed the risks, benefits and potential complications of the planned procedure, and the risks, benefits and potential complications of alternative treatments with the patient/family who express understanding and wish to proceed.

TIME _____ ☐ AM ☐ PM **DATE** _____ Physician signature _____ Pager number _____

INTERPRETATION SERVICES

I certify that I have interpreted, to the best of my ability, into and from the participant's stated primary language, _____, all oral presentations made by all of those present during the informed consent discussion.

TIME _____ ☐ AM ☐ PM **DATE** _____ Interpreter signature _____

Interpreter name (print) _____

