BAYLOR GENETICS

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CONNECT

PRESEEK NON-INVASIVE PRENATAL SCREENING CONSENT FORM

Fetus of: _____ (Patient Last Name) _____ (Patient First Name) _____ (MI) ____ / ____ / ____ (Date of Birth MM / DD / YYYY) _____ (Biological Sex)

INFORMED CONSENT FOR PRESEEK TESTING

PreSeek is a cell-free fetal DNA noninvasive prenatal screen that analyzes fetal disorders in maternal blood. PreSeek screens for genetic disorders that can cause skeletal dysplasias, cardiac defects, multiple congenital anomalies and/or intellectual defects due to variants in the genes included (see list). The biological mother's sample is required for this test; the test cannot be performed without samples from the biological mother. This test is not appropriate for individuals who had a blood transfusion in the last month or a bone marrow transplant.

PreSeek will report only pathogenic and likely pathogenic variants and will not report variants of uncertain significance or benign variants. PreSeek detects predominantly variants which occur with increasing frequency as paternal age advances. However, this testing may possibly indicate that a parent of the fetus has or is predisposed to one of these genetic disorders tested. PreSeek does not screen for fetal chromosome aneuploidies or other copy number abnormalities.

PreSeek should be ordered by a healthcare provider who should provide appropriate genetic counseling to the patient prior to ordering the test and after receiving results. Results are confidential and will only be disclosed to the ordering healthcare providers, the patient upon request, and third party payers if required. Positive screening results should always be followed-up with an invasive, diagnostic test before any medical decisions are made.

I understand that:

1. If the PreSeek results are positive, I should consult my physician or genetic counselor and consider further invasive fetal testing.
2. The PreSeek results may inform me of a pathogenic or likely pathogenic variant that is present in only myself, but may not be present in the fetus. This information is important for me to understand the complete risk for this pregnancy. I understand that a negative PreSeek result does not rule out the possibility of the fetus, myself, or my partner of having a genetic disorder.
3. It is possible that additional information may come to light during these studies regarding family relationships. For example, data may suggest that family relationships are not as reported, such as misattributed parentage (e.g. maternal identity is different than indicated on the requisition). Variant interpretation is based on the family history and the family relationship information provided to Baylor Genetics by the ordering healthcare provider.
4. Information including results, indications for testing and clinical status obtained from the PreSeek test may be shared with healthcare providers, scientists and health are databases or used in scientific publications or presentations, but the personal identifying information of all persons studied will not be revealed in such data sharing or publications/presentations.

All specimens will be retained in the laboratory in accordance with the laboratory retention policy and, if from New York State, will be discarded within 60 days.

RESEARCH & RECONTACT CONSENT

For more information on research at Baylor Genetics, please visit baylorgenetics.com. Please read the below statements carefully and check the appropriate box.

Note: If left blank, consent is interpreted as "NO."

☐ I agree to use of my de-identified specimen for research to improve genetic testing for all patients and contribute to scientific research.

☐ I am a New York State Resident, and I give Baylor Genetics permission to store my specimen in accordance to the laboratory retention policy for internal quality assurance and possible research studies.

☐ In addition to agreeing above, I agree to be contacted by Baylor Genetics regarding research opportunities.

PATIENT AUTHORIZATION

By signing this statement of consent, I acknowledge that I have read and understand the informed consent for genetic testing. I have received appropriate explanations from my physician regarding the purpose, scope, type and significance of the planned genetic testing and achievable results. All my questions have been answered and I have had the necessary time to make an informed decision about the genetic test.

I give permission to Baylor Genetics to conduct genetic testing as recommended by my physician.

_____ (Maternal Patient's Name) _____ (Maternal Patient's Signature) ____ / ____ / ____ (Date MM / DD / YYYY)