

PRESEEK NON-INVASIVE PRENATAL SCREENING REQUISITION

PATIENT INFORMATION (COMPLETE ONE FORM FOR EACH PERSON TESTED)

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

Address _____ City _____ State _____ Zip _____ Phone _____

Accession # _____ Hospital / Medical Record # _____

Patient discharged from the hospital/facility: Yes No

Genetic Sex: Female Male Unknown

Gender identity (if different from above): _____

REPORTING RECIPIENTS

Ordering Physician _____ Institution Name _____

Email (Required for International Clients) _____ Phone _____ Fax _____

ADDITIONAL RECIPIENTS

Name _____ Email _____ Fax _____

Name _____ Email _____ Fax _____

PAYMENT (FILL OUT ONE OF THE OPTIONS BELOW)

SELF PAYMENT

Pay With Sample Bill To Patient

INSTITUTIONAL BILLING

Institution Name _____ Institution Code _____ Institution Contact Name _____ Institution Phone _____ Institution Contact Email _____

INSURANCE

Do Not Perform Test Until Patient is Aware of Out-Of-Pocket Costs (excludes prenatal testing)

REQUIRED ITEMS 1. Copy of the Front/Back of Insurance Card(s) 2. ICD10 Diagnosis Code(s) 3. Name of Ordering Physician 4. Insured Signature of Authorization

Name of Insured _____ Insured Date of Birth (MM / DD / YYYY) _____ Patient's Relationship to Insured _____ Phone of Insured _____

Address of Insured _____ City _____ State _____ Zip _____

Primary Insurance Co. Name _____ Primary Insurance Co. Phone _____ Primary Member Policy # _____ Primary Member Group # _____

By signing below, I hereby authorize Baylor Genetics to provide my insurance carrier any information necessary, including test results, for processing my insurance claim. I understand that I am responsible for any co-pay, co-insurance, and unmet deductible that the insurance policy dictates, as well as any amounts not paid by my insurance carrier for reasons including, but not limited to, non-covered and non-authorized services. I understand that I am responsible for sending Baylor Genetics any and all payments that I receive directly from my insurance company in payment for this test. Please note that Medicare does not cover routine screening tests.

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

STATEMENT OF MEDICAL NECESSITY (REQUIRED)

This test is medically necessary for the risk assessment, diagnosis, or detection of a disease, illness, impairment, symptom, syndrome, or disorder. The results will determine my patient's medical management and treatment decisions. The person listed as the Ordering Physician is authorized by law to order the test(s) requested herein. I confirm that I have provided genetic testing information to the patient and they have consented to genetic testing.

Physician's Printed Name _____ Physician's Signature _____ Date (MM / DD / YYYY) _____

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ETHNICITIES

BIOLOGICAL MATERNAL ETHNICITY

- | | | |
|--------------------------------------------------------|-------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| <input type="radio"/> African American | <input type="radio"/> Hispanic American | <input type="radio"/> Pacific Islander (Philippines, Micronesia, Malaysia, Indonesia) |
| <input type="radio"/> Ashkenazi Jewish | <input type="radio"/> Mennonite | <input type="radio"/> South Asian (India, Pakistan) |
| <input type="radio"/> East Asian (China, Japan, Korea) | <input type="radio"/> Middle Eastern (Saudi Arabia, Qatar, Iraq, Turkey) | <input type="radio"/> Southeast Asian (Vietnam, Cambodia, Thailand) |
| <input type="radio"/> Finnish | <input type="radio"/> Native American | <input type="radio"/> Southern European Caucasian (Spain, Italy, Greece) |
| <input type="radio"/> French Canadian | <input type="radio"/> Northern European Caucasian (Scandinavian, UK, Germany) | <input type="radio"/> Other (Specify): _____ |

SAMPLE SPECIFICATIONS TABLE

PATIENT	ABBREVIATION	SAMPLE NAME	RECOMMENDED AMOUNT	SHIPPING INSTRUCTIONS	SPECIAL NOTES
Maternal	ST	Streck Tube	Two 10mL tubes	Ship at room temperature in an insulated container by overnight courier. Do not heat or freeze.	We recommend that the sample is received in the lab within 72 hours after collection. Samples received in the lab greater than 7 days after date of collection will be rejected.

SAMPLE ICD-10 DIAGNOSIS CODES

The ICD-10 diagnosis code(s) must be defined for the most detailed level of specificity available. The following list of commonly used ICD-10 codes for prenatal testing is not complete. Please refer to the ICD-10 manual for a complete listing. These codes are being provided for informational purposes only; it is ultimately the responsibility of the ordering provider to select the appropriate ICD-10 code supported by the patient's medical record.

Advanced Maternal Age: Primigravida [009.511(1st trimester); 009.512(2nd trimester); 009.513(3rd trimester); 009.519 (Unspecified trimester)]
 Advanced Maternal Age: Multigravida [009.521(1st trimester); 009.522(2nd trimester); 009.523(3rd trimester); 009.529 (Unspecified trimester)]
 Abnormal Serum Biochemical Screen: 028.1
 Ultrasound Finding: 035.1XX0; 028.3, 028.4, 035.9XX0, 035.9XX1, 035.9XX9
 Positive Test Result for Aneuploidy: 028.5, 028.8, 028.9, 035.1XX1, 035.1XX9

Personal Family History:
 Prior pregnancy with trisomy [009.291(1st trimester); 009.292(2nd trimester); 009.293(3rd trimester); 009.299 (Unspecified trimester)]
 Other High Risk Pregnancies [009.891 (1st trimester); 009.892 (2nd trimester); 009.893 (3rd trimester); 009.899 (Unspecified trimester)]
 Robertsonian translocation [Q95.0 (Balanced Translocation) Q95.1 (Chromosome Inversion)]

GENES ANALYZED ON PRESEEK

CRANIOSYNOSTOSIS SYNDROMES

GENE	DISORDER
FGFR2	Antley-Bixler syndrome without genital anomalies or disordered steroidogenesis, Apert syndrome, Crouzon syndrome, Jackson-Weiss syndrome, Pfeiffer syndrome type 1/2/3

SKELETAL DISORDERS

GENE	DISORDER
FGFR3	Achondroplasia, CATSHL syndrome, Crouzon syndrome with acanthosis nigricans, Hypochondroplasia, Muenke syndrome, Thanatophoric dysplasia, types I and II
COL1A1	Ehlers-Danlos syndrome, classic and type VIIA, Osteogenesis imperfecta, types I, II, III, and IV
COL1A2	Ehlers-Danlos syndrome, cardiac valvular form and type VIIB, Osteogenesis imperfecta, types II, III, and IV

NOONAN SPECTRUM DISORDERS

GENE	DISORDER
BRAF	Cardiofaciocutaneous syndrome 1
CBL	Noonan syndrome-like disorder with or without juvenile myelomonocytic leukemia (NSLL)
HRAS	Costello syndrome/Noonan syndrome
KRAS	Noonan syndrome/cancers
MAP2K1	Cardiofaciocutaneous syndrome 3
MAP2K2	Cardiofaciocutaneous syndrome 4
NRAS	Noonan syndrome 6/cancers
PTPN11	Noonan syndrome 1/LEOPARD syndrome/cancers
RAF1	Noonan syndrome 5/LEOPARD syndrome 2
RIT1	Noonan syndrome 8
SHOC2	Noonan syndrome-like disorder with loose anagen hair
SOS1	Noonan syndrome 4
SOS2	Noonan syndrome 9

SYNDROMIC DISORDERS

GENE	DISORDER
JAG1	Alagille syndrome
CHD7	CHARGE syndrome
HDAC8	Cornelia de Lange syndrome 5
NIPBL	Cornelia de Lange syndrome 1
RAD21	Cornelia de Lange syndrome 4
SMC1A	Cornelia de Lange syndrome 2
SMC3	Cornelia de Lange syndrome 3
TSC1	Tuberous sclerosis 1
TSC2	Tuberous sclerosis 2
CDKL5	Epileptic encephalopathy, early infantile, 2
MECP2	Rett syndrome
NSD1	Sotos syndrome 1
SYNGAP1	Intellectual disability, type 5

INFORMED CONSENT FOR PRESEK NON-INVASIVE PRENATAL SCREENING

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

TEST INFORMATION

This consent form will provide you with information regarding genetic testing, which you should discuss with your healthcare provider or a genetic counselor. To assist you in understanding the reason for this testing, we have provided information about the testing process and potential results below.

The purpose of genetic testing is to determine if a genetic disease may be present or if there is an increased risk for a genetic disease to occur in a patient or their family. DNA is the genetic material that we receive from our parents. Genes are made of DNA and are the instructions for maintaining the health of our body. Each person has a unique set of DNA and most of the differences in our DNA do not impact our health. Genetic testing analyzes DNA to find any abnormal changes (mutations also called variants) that might cause disease, make it more likely to develop disease, and/or increase the chance of having a child affected by disease.

The testing ordered by your healthcare provider can determine if you or your child have a variant associated with a genetic disease. "Your child" can also mean your unborn child, for the purposes of this consent.

Depending on why genetic testing is needed, you might be tested for:

- A known variant that has already been found in your family
- A single gene or variant that causes a specific, suspected disease.
- Multiple genes at the same time. These genes might cause similar diseases or might cause diseases that are unrelated to each other.
- Multiple types of testing that each test for different variants.

RESULTS

There are several types of test results that may be reported including:

- Positive: Positive or "abnormal" results mean there is a change in the DNA found that is related to your/your child's medical issues or that you/your child are at an increased risk of developing a disease in the future. It is possible to test positive for more than one variant. Positive results might include pathogenic variants (variants known to be associated with disease) and likely pathogenic variants (variants that are likely to be associated with disease).
- Negative: Negative or "normal" results mean no relevant variants related to your/your child's medical issues were detected or that you/your child are not expected to be at an increased risk for developing a disease in the future. This might indicate that there are no variants associated with disease in the gene(s) tested. Genetic testing, while highly accurate, might not detect a variant present in the gene(s) tested. This can be due to limitations of the information available about the gene(s) being tested, or limitations of the testing technology.
- Variant of Uncertain Significance: Testing can detect variant(s) in DNA which we do not yet fully understand. These are also referred to as variants of uncertain significance (VUS). Additional testing may be recommended for you or your family if a VUS is identified in a gene that may be associated with your/your child's medical condition.
- Secondary / Incidental Findings: Testing can sometimes detect a variant in a person's DNA unrelated to the reason for testing. If this variant is expected to have medical or reproductive significance, it is called a secondary or incidental finding.

CONSIDERATIONS AND LIMITATIONS

- This consent form cannot be used for whole exome sequencing (WES), whole genome sequencing (WGS), or Huntington's disease testing. These tests have specific consents that are located at <https://www.baylorgenetics.com/consent/>.
- Results may indicate you have a genetic disease, are at increased risk to develop a genetic disease, and/or be at an increased risk to have a child with a genetic disease. It is important to understand that genetic tests, even if negative, cannot rule out every variant. It is not possible to exclude risks for all genetic diseases for you and your family members.
- Depending on the type of genetic testing performed and the results, additional genetic testing or other testing may be needed to fully understand the likelihood of your developing the disease or the severity of the disease. This additional testing might be needed for you/your child or other members of your family.
- It is recommended that you discuss genetic testing with your healthcare provider or genetic counselor before signing this consent and again after results are made available.
- It may not always be possible to complete testing, as sometimes the sample does not have enough DNA to perform testing or other reasons. In these cases, another sample may need to be sent to the laboratory to perform testing.

PATIENT CONFIDENTIALITY AND SPECIMEN RETENTION

- If several family members are tested, the correct interpretation of the results depends on the information provided about the relationships amongst family members. In rare cases, genetic testing can reveal that the true biological relationships in a family are not as they were reported. If a difference is identified, it may be necessary to share this information with the healthcare provider who ordered the testing.

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PATIENT CONFIDENTIALITY AND SPECIMEN RETENTION (CONT.)

- Genetic testing is highly accurate, however in rare cases, inaccurate results may occur. Reasons for this include, but are not limited to, mislabeled samples, inaccurate reporting of clinical/medical information, or rare technical errors.
- If you sign this consent form, but you no longer wish to have your sample(s) tested, you can contact the healthcare provider who ordered the test to cancel the test. If you wish to cancel testing, the laboratory must be notified of the cancellation request before 5 PM CST the business day after the sample has begun testing. If the laboratory is not notified of your cancellation request until after this time, you will be charged for the full cost of the test.
- Only Baylor Genetics and Baylor Genetics contracted partners will have access to the sample(s) provided to conduct the requested testing. Results will only be released to the following person(s): (i) a licensed healthcare provider, (ii) those authorized in writing, (iii) the patient or their personal representative, and (iv) those allowed access to test results by law. I understand that I have the right to access any test results directly from Baylor Genetics by providing a written request. I also understand that laboratory raw data, while not routinely released as part of the testing process, can be requested by providing a written request or HIPAA Authorization Form.
- In rare cases, persons with genetic diagnoses have experienced problems with insurance coverage and employment. The U.S. Federal Government has enacted several laws that prohibit discrimination based on genetic test results by health insurance companies and employers. In addition, these laws prohibit unauthorized disclosure of this information. For more information, you can visit www.genome.gov/10002077.
- Samples will be retained in the laboratory in accordance with the laboratory retention policy.
- After testing is complete, the de-identified submitted specimen may be used for test development and improvement, internal validation, quality assurance, and training purposes. DNA specimens are not returned to individuals or to referring health care providers unless specific prior arrangements have been made.
- Samples from residents of New York State will not be included in research studies without your written consent and will not be retained for more than 60 days after receipt of the sample. No tests other than those authorized shall be performed on the biological sample.
- By signing this consent form, I understand and agree that variants identified may also be submitted to public databases, such as ClinVar. Such submission serves to contribute knowledge to the medical community. I understand that limited clinical information is also required for the submission of information to ClinVar's database and further that the contents of this limited clinical information may, although unlikely, include information that may identify me personally.
- It is possible that even if the test identifies the underlying genetic cause for the disease in your family, this information may not help in predicting the progression of disease or change management or treatment of disease.

FINANCIAL AGREEMENT AND GUARANTEE

By signing this consent form, I accept full and complete financial responsibility for all genetic testing ordered by my healthcare provider. For insurance billing, I hereby authorize Baylor Genetics to bill my health insurance plan on my behalf, and further authorize Baylor Genetics to release any information to my insurance carrier which is reasonably required for billing. I additionally designate Baylor Genetics as my designated representative for purposes of appealing any denial of benefits by my insurance carrier. I irrevocably assign associated payment to Baylor Genetics, and direct that payment be made directly to Baylor Genetics. I understand that my out-of-pocket costs may be different than the estimated amount indicated to me by Baylor Genetics as part of a verification of benefits investigation. I agree to be financially responsible for all amounts as indicated on the explanation of benefits issued by my health insurance plan. If my insurance provider sends a payment directly to me for unpaid services performed by Baylor Genetics on my behalf, I agree to endorse the insurance check as appropriate and forward such check to Baylor Genetics within thirty (30) days of receipt thereof, as payment towards Baylor Genetics' claim for services rendered. If I do not have health insurance, I agree to pay for the full cost of the genetic testing that was ordered by my healthcare provider and billed to me by Baylor Genetics.

I understand that a completed Advance Beneficiary Notice (ABN) is required for Medicare patients if the service is deemed not medically necessary.

RECONTACT FOR RESEARCH CONSENT

Baylor Genetics participates in research relating to health, disease prevention, drug development, and other scientific purposes. Baylor Genetics may contact patients or their provider(s) directly as part of this research. I agree to allow Baylor Genetics to contact me or my provider(s) about possible research involving the sample(s) and/or information associated with this testing. I understand that patients generally receive no compensation for this participation in research. For more information on research at Baylor Genetics, please visit baylorgenetics.com.

If I wish to opt out of being recontacted for research purposes by Baylor Genetics, I understand that I may check the box below:

Please do not contact me regarding any research that uses information obtained from this testing.

For any research I may be contacted about, I prefer contact through the following methods (please check all that apply – if no choices are selected, contact will be made via secure email if possible):

Email Phone Mail

INFORMED CONSENT FOR PRESEK NON-INVASIVE PRENATAL SCREENING

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

PATIENT AUTHORIZATION

By signing this statement of consent, I acknowledge that I have read, understand, and hereby grant my informed consent for genetic testing. I have received appropriate explanations from my healthcare provider about the planned genetic test(s) and possible results. I have been informed by my healthcare provider about the availability and importance of genetic counseling and have been provided with written information identifying a genetic counselor or medical geneticist who can provide such counseling services. All my questions have been answered and I have had the necessary time to make an informed decision about the genetic test(s).

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

Patient's Printed Name Patient's Signature Date (MM / DD / YYYY)

Patient's Parent / Personal Representative* Name Patient's Parent / Personal Representative Signature Date (MM / DD / YYYY)

Relationship of Personal Representative to the Patient Ordering Provider's Signature Date (MM / DD / YYYY)

*If you are signing as a person with legal authority to act on behalf of the patient, you may be required to provide evidence of your authority.