BAYLOR GENETICS
2450 HOLCOMBE BLVD.
SUITE 2210
HOUSTON, TX 77021-2024

PHONE
1.800.411.4363
FAX
1.800.434.9850

CONNECT

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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IMPORTANT NOTES

- The biological mother's sample is REQUIRED for PreSeek testing to be performed.
- PreSeek can only be performed on singleton pregnancies. Furthermore, PreSeek cannot be performed on pregnancies in which there has been a fetal demise, vanishing twin, or reduction.

MATERNAL SPECIMEN INFORMATION

_____ (Maternal Last Name) _____ (Maternal First Name) _____ (MI) ____ / ____ / ____ (Maternal Date of Birth MM / DD / YYYY)

TEST OPTION

☐ 21200 PreSeek (Maternal)

SAMPLE

Date of Collection:

____ / ____ / ____
MM DD YYYY

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 TYPE *

● Streck Tube

# of Streck Tubes: _____

Sample requirement is 2 Streck tubes, each with a minimum of 8mL of blood.

GESTATIONAL INFORMATION (REQUIRED)

Patient must be at least 9 weeks gestation at the time of blood draw.

_____ Maternal Height ○ ft/in ○ cm

_____ Maternal Weight ○ lbs ○ kgs

Gestational Age on DOC: _____ Weeks _____ Days

Dating Method:

○ LMP ____ / ____ / ____ (MM / DD / YYYY)

○ U/S ____ / ____ / ____ (MM / DD / YYYY)

Was egg donor used? ○ Yes ○ No

Was sperm donor used? ○ Yes ○ No

CLINICAL FINDINGS

☐ Advanced Maternal Age 35+ years (at delivery) for singleton pregnancies

Primigravida	○ 009.511 (1st Tri)	Multigravida	○ 009.521 (1st Tri)
	○ 009.512 (2nd Tri)		○ 009.522 (2nd Tri)
	○ 009.513 (3rd Tri)		○ 009.523 (3rd Tri)

☐ Advanced Paternal Age

☐ Abnormal Serum Biochemical Screening: ○ O28.1 ○ Other: _____

☐ Ultrasound Finding (Attach Report and Specify): ○ O35.1XX0

☐ Maternal - Personal or Family History of a genetic disorder (Specify):

☐ Egg Donor - Personal or Family History of a genetic disorder (Specify):

☐ Paternal - Personal or Family History of a genetic disorder (Specify):

☐ Sperm Donor - Personal or Family History of a genetic disorder (Specify):

☐ Low Risk Pregnancy/ Parental Concern:

Primigravida ○ Z34.00 Multigravida ○ Z34.80

FOR SAMPLES SUBMITTED FROM NEW YORK STATE

MOTHER'S INITIALS _____

Specimen Retention: My sample shall be destroyed at the end of the testing process or not more than 60 days after completion of testing. However, I hereby authorize the lab to retain my sample(s) for a longer retention in accordance to the laboratory retention policy for internal laboratory quality assurance studies and possible research testing.

INDICATION FOR TESTING

☐ Abnormal NIPT (Specify ICD-10 Code): _____

○ TRI 21 ○ TRI 18 ○ TRI 13 ○ Other: _____

☐ Other (Specify ICD-10 Code): _____

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ETHNICITIES

BIOLOGICAL MATERNAL ETHNICITY

- ◯ African American
- ◯ Ashkenazi Jewish
- ◯ East Asian (China, Japan, Korea)
- ◯ Finnish
- ◯ French Canadian
- ◯ Hispanic American
- ◯ Mennonite
- ◯ Middle Eastern (Saudi Arabia, Qatar, Iraq, Turkey)
- ◯ Native American
- ◯ Northern European Caucasian (Scandinavian, UK, Germany)
- ◯ Pacific Islander (Philippines, Micronesia, Malaysia, Indonesia)
- ◯ South Asian (India, Pakistan)
- ◯ Southeast Asian (Vietnam, Cambodia, Thailand)
- ◯ Southern European Caucasian (Spain, Italy, Greece)
- ◯ 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 [O09.511(1st trimester); O09.512(2nd trimester); O09.513(3rd trimester); O09.519 (Unspecified trimester)]
Advanced Maternal Age: Multigravida [O09.521(1st trimester); O09.522(2nd trimester); O09.523(3rd trimester); O09.529 (Unspecified trimester)]
Abnormal Serum Biochemical Screen: O28.1
Ultrasound Finding: O35.1XX0; O28.3, O28.4, O35.9XX0, O35.9XX1, O35.9XX9
Positive Test Result for Aneuploidy: O28.5, O28.8, O28.9, O35.1XX1, O35.1XX9

Personal Family History:
- Prior pregnancy with trisomy [O09.291(1st trimester); O09.292(2nd trimester); O09.293(3rd trimester); O09.299 (Unspecified trimester)]
- Other High Risk Pregnancies [O09.891 (1st trimester); O09.892 (2nd trimester); O09.893 (3rd trimester); O09.899 (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

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

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

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

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

GENERAL GENETIC TESTING CONSENT

This consent form cannot be used for whole exome sequencing (WES), whole genome sequencing (WGS), biochemical testing, or Huntington disease testing. Consent forms for other tests are located at Baylor Genetics' website (https://www.baylorgenetics.com/consent/).

For the purposes of this consent, "I", "my", "you", and "your" can refer to you, your child, your unborn child, or other individual you are the legal representative of.

TEST INFORMATION

Your healthcare provider (doctor, genetic counselor, or other person with medical training) wants to order one or more tests to find a cause for your health issues. This testing can see if there is a cause for your health issues or if there is an increased chance for a health issue to happen to you or your family. Some of these tests look for changes, called variants, in a person's DNA. DNA is our genetic material. You might have testing for variants in one or more genes, specific parts of DNA that are needed for our health. Variants can also be found in other places in the genome (all of the DNA that a person has). Some tests might look for changes in proteins or analytes that cause health issues. The testing ordered will depend on your health issues as well as what is already known about you and your family's genetics. These tests may also explain health issues that your family may have. Even if this test finds the cause of your health issues, this may not help treat or manage those issues.

Before you sign this consent form, you should speak with your healthcare provider. They can help you understand this testing and what it means for your health.

TEST RESULTS

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

- **Positive:** A variant in the DNA was found that is related to your health issues or a health issue that you are at an increased risk of having in the future. These changes that cause disease are also known as pathogenic variants.
- **Negative:** No variants in the DNA were found that are related to your health issues or that would increase your risk of a health issue in the future.
- **Variant of Uncertain Clinical Significance (VUS):** A variant in the DNA was found that we do not know its effect, if any, on health. More testing may be needed for you or your family if a VUS is found that may be associated with your health issues.
- **Secondary and Incidental Findings:** Testing can sometimes find a variant in the DNA not related to the reason for testing. If this result is expected to affect your health, it is called a secondary or incidental finding.

CONSIDERATIONS AND LIMITATIONS

- You should speak with your provider before signing this consent form to understand the risks, benefits, and alternatives to testing.
- Testing may show you have, or are at increased chance of having, a health issue. It may show that you have an increased chance of having a child with a health issue.
- Even if the variant(s) causing your health issues are found, how these issues might progress or improve with treatment might not be known. Affected family members with the same variant might not be affected like you are.
- Depending on the results of testing, more testing may be needed to understand these results. This testing might be needed for you and/or other family members.
- A negative result does not rule out the chance for health issues. Our knowledge of variants and how they cause disease may change over time as we learn more about genetics. Testing has limitations to what it can find as well.
- Certain factors may lead to incorrect results. These include mislabeled samples, incorrect information in the test order, and rare technical errors.
- More sample may be needed from you if the first sample is not sufficient to complete testing.

PATIENT CONFIDENTIALITY AND SAMPLE RETENTION

- If several family members are tested, knowing the correct biological relationships among them is important. In rare cases, testing can show that family members are not related as expected. If this is found, we may contact the provider who ordered your testing.
- If this testing is requested to be cancelled after the order and sample are sent to the laboratory, please see our Test Cancellation Policy at www.baylorgenetics.com/cancel-test/.
- Only Baylor Genetics and its contracted partners will have access to your sample for the ordered testing. Results from testing will only be released to: (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. You have the right to access your test results from Baylor Genetics by providing a written request. You also have the right to request raw data obtained from your sample by providing a written request or HIPAA Authorization Form.
- In rare cases, people with genetic diseases may have problems with health insurance and employment. The U.S. Federal Government has several laws that prohibit discrimination based on test results by health insurance companies and employers. These laws also prohibit unauthorized disclosure of this information. For more information, please visit www.genome.gov/10002077.
- Samples will be kept in the laboratory based on our retention policy. Once testing completes, de-identified sample may be used for test development, quality assurance, and training purposes. Samples are not returned to patients or providers unless requested prior to testing. You and your heirs will not receive payments, benefits, or rights to any resulting products or discoveries.
- The information from your testing may be used in scientific research, publications or presentations, but your specific identity will not be revealed. We may contact your provider to obtain more clinical information about you. Baylor Genetics also performs other types of scientific research and may contact you to see if you would like to be involved.
- Variants found may be submitted to databases. The medical community uses these databases to collect information about how variants might cause disease to improve testing and treatment for patients. An example is ClinVar, a free, public archive of reports on human genetics. Limited clinical information may need to be shared with these databases. In rare cases, this information may be enough to allow you or your family members to be identified.
- For more information on privacy practices at Baylor Genetics, please visit www.baylorgenetics.com/privacy-practices/.

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FOR SAMPLES FROM NEW YORK STATE RESIDENTS

Samples from New York State residents shall not be included in research without written consent. Samples will not be retained for more than sixty (60) days after receipt by Baylor Genetics, unless authorized by marking below. No tests other than those authorized shall be performed on the samples.

☐ I authorize Baylor Genetics to retain sample(s) longer based on our retention policy for test development, quality assurance, and training purposes.

FINANCIAL AGREEMENT

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. I 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. Please note, some payers may not cover certain screening tests.

If my health insurer does not cover the test or I do not have health insurance, I have received a good faith estimate of the cost for the genetic testing ordered by my provider and agree to pay for the cost of the genetic testing billed to me by Baylor Genetics based on that good faith estimate. More information is available in Baylor Genetics' No Surprises Act and Good Faith Estimate Notice located at https://www.baylorgenetics.com/no-surprises-act/.

A Medicare Advance Beneficiary Notice (ABN) is required for services Medicare identifies as not medically necessary.

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

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

*If you are signing on behalf of the patient as the parent(s) and/or person with legal authority to act on behalf of the patient or parent, you may be required to provide evidence of your authority.