

PRESEEK NON-INVASIVE PRENATAL SCREENING REQUISITION

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

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) ☐ 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: ☐ 028.1 ☐ Other: _____

☐ Ultrasound Finding (Attach Report and Specify): ☐ 035.1XX0

☐ 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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/

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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 [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		SKELETAL DISORDERS	
GENE	DISORDER	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	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		SYNDROMIC DISORDERS	
GENE	DISORDER	GENE	DISORDER
BRAF	Cardiofaciocutaneous syndrome 1	JAG1	Alagille syndrome
CBL	Noonan syndrome-like disorder with or without juvenile myelomonocytic leukemia (NSLL)	CHD7	CHARGE syndrome
HRAS	Costello syndrome/Noonan syndrome	HDAC8	Cornelia de Lange syndrome 5
KRAS	Noonan syndrome/cancers	NIPBL	Cornelia de Lange syndrome 1
MAP2K1	Cardiofaciocutaneous syndrome 3	RAD21	Cornelia de Lange syndrome 4
MAP2K2	Cardiofaciocutaneous syndrome 4	SMC1A	Cornelia de Lange syndrome 2
NRAS	Noonan syndrome 6/cancers	SMC3	Cornelia de Lange syndrome 3
PTPN11	Noonan syndrome 1/LEOPARD syndrome/cancers	TSC1	Tuberous sclerosis 1
RAF1	Noonan syndrome 5/LEOPARD syndrome 2	TSC2	Tuberous sclerosis 2
RIT1	Noonan syndrome 8	CDKL5	Epileptic encephalopathy, early infantile, 2
SHOC2	Noonan syndrome-like disorder with loose anagen hair	MECP2	Rett syndrome
SOS1	Noonan syndrome 4	NSD1	Sotos syndrome 1
SOS2	Noonan syndrome 9	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

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/.

INFORMED CONSENT FOR PRESEK NON-INVASIVE PRENATAL SCREENING

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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.