BAYLOR GENETICS

BAYLOR GENETICS
2450 HOLCOMBE BLVD.
GRAND BLVD. RECEIVING DOCK
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

Biological 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)

BAYLOR GENETICS

BAYLOR GENETICS
2450 HOLCOMBE BLVD.
GRAND BLVD. RECEIVING DOCK
HOUSTON, TX 77021-2024

PHONE
1.800.411.4363
FAX
1.800.434.9850

CONNECT

PRESEEK NON-INVASIVE PRENATAL SCREENING REQUISITION

Fetus of: _____ (Patient Last Name) _____ (Patient First Name) _____ (MI) ____ / ____ / ____ (Date of Birth MM / DD / YYYY) _____ (Biological 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	◯ O09.511 (1st Tri)	Multigravida	◯ O09.521 (1st Tri)
	◯ O09.512 (2nd Tri)		◯ O09.522 (2nd Tri)
	◯ O09.513 (3rd Tri)		◯ O09.523 (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):

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

◯ TRI 21 ◯ TRI 18 ◯ TRI 13 ◯ Other: _____

☐ Low Risk Pregnancy/ Parental Concern:

Primigravida ◯ Z34.00 Multigravida ◯ Z34.80

☐ Other (Specify ICD-10 Code): _____

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.

BAYLOR GENETICS
2450 HOLCOMBE BLVD.
GRAND BLVD. RECEIVING DOCK
HOUSTON, TX 77021-2024

PHONE
1.800.411.4363
FAX
1.800.434.9850

CONNECT

PRESEEK NON-INVASIVE PRENATAL SCREENING REQUISITION

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

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

BAYLOR GENETICS

BAYLOR GENETICS
2450 HOLCOMBE BLVD.
GRAND BLVD. RECEIVING DOCK
HOUSTON, TX 77021-2024

PHONE
1.800.411.4363
FAX
1.800.434.9850

CONNECT

INFORMED CONSENT FOR PRESEEK NON-INVASIVE PRENATAL SCREENING

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)