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

PRENATAL COMPREHENSIVE 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 #

Multiple gestation? ◯ Yes ◯ No
If yes, sample from fetus _____

Donor used? Please specify: _____

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 #

_____ Name of Insured _____ / _____ / _____ Insured Date of Birth (MM / DD / YYYY)

_____ Patient's Relationship to Insured _____ Phone of Insured

_____ Address of Insured

_____ City _____ State _____ Zip

_____ Secondary Insurance Co. Name _____ Secondary Insurance Co. Phone

_____ Secondary Member Policy # _____ Secondary 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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Fetus of: _____ (Patient Last Name) _____ (Patient First Name) _____ (MI) ____ / ____ / ____ (Date of Birth MM / DD / YYYY) _____ (Genetic Sex)

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

Date of Collection (MM / DD / YYYY) (REQUIRED) ____ / ____ / _____

SAMPLE TYPE

- ◯ Amniotic Fluid _____ cc
- ◯ CVS _____ mg ☐ TA ☐ TC
- ◯ Fetal Blood _____ cc
- ◯ Cultured Amniocytes
- ◯ Cultured CVS

Additional Cultures to be sent later: ◯ Yes ◯ No

Cultures will be sent from: _____

GESTATIONAL INFORMATION*

U/S Date (MM/DD/YYYY) ____ / ____ / _____

Gestational Age on U/S Date: _____ weeks _____ days

LMP Date (MM/DD/YYYY) ____ / ____ / _____

* NOTE: U/S dating increases Amniotic Fluid Alpha Fetoprotein (AFAFP) and Acetylcholinesterase (AChE) performance.

PARENTAL AND FAMILIAL SAMPLES

Note: Parental samples are required for Chromosomal Microarray Analysis (CMA) and positive control samples are required for known familial variant testing.

- ◯ Maternal ____ / ____ / _____ (Date of Collection MM/DD/YYYY)
- ◯ Paternal ____ / ____ / _____ (Date of Collection MM/DD/YYYY) _____ (Paternal Last Name) _____ (Paternal First Name) ____ / ____ / _____ (Date of Birth MM/DD/YYYY)
- ◯ Other Family Member ____ / ____ / _____ (Date of Collection MM/DD/YYYY) _____ (Other Family Member Last Name) _____ (Other Family Member First Name) ____ / ____ / _____ (Date of Birth MM/DD/YYYY)

Note: Parental and familial samples should be collected in an EDTA tube (5-7cc) for blood or buccal swab and labeled with name and date of birth.

INDICATION FOR TESTING (REQUIRED)

ICD-10 Diagnosis Code(s): _____

- ◯ Pregnancy at Risk for Specific Genetic Disorder (Complete Known Familial Variant/Disorder Specific Prenatal Testing section on the next page)
- ◯ Advanced Maternal Age (AMA)
- ◯ Abnormal Maternal Screen
  - ☐ NTD ☐ TRI 21 ☐ TRI 18 ☐ Other:
- ◯ Abnormal cell-free DNA (attach report)
  - ☐ TRI 13 ☐ TRI 21 ☐ TRI 18 ☐ Other: _____
- ◯ Abnormal U/S (Specify) _____
- ◯ Multiple Pregnancy Losses
- ◯ Parental Concern
- ◯ Other Indication (Attach Report and Specify) _____

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

KNOWN FAMILIAL VARIANT/DISORDER SPECIFIC PRENATAL TESTING

Note: Prior to ordering testing for any of the disorders listed, please visit our Prenatal Sample Requirements page on our website (www.baylorgenetics.com/prenatal-sample-requirements/). For complex testing questions or known familial variant testing, genetic counselors may be reached via email at gc@baylorgenetics.com or by phone at 1-800-411-4363.

- ☐ 1522 Custom Sequence Analysis - Prenatal
- ☐ 6099 Huntington Disease Repeat Expansion Analysis
- ☐ 6100 IKBKG Common Deletion Analysis
- ☐ 6105 Myotonic Dystrophy Type 1 Repeat Expansion Analysis
- ☐ 6109 MECP2 Deletion/Duplication Analysis
- ☐ 6351 DMD Deletion/Duplication Analysis
- ☐ 6574 FMR1 (Fragile X) CGG Repeat Expansion Analysis

_____ Name of Baylor Genetic Counselor

_____ / _____ / _____ Date (MM/DD/YYYY)

_____ Gene Name

_____ Baylor Genetics Family #

Variant Information: c. _____ p. _____

◯ (REQUIRED) Attached Familial Variant Report

NOTICE FOR PRENATAL BIOCHEMICAL AND DNA TESTS: Please be aware that our specimen requirements and quality control measures are compliant with the American College of Medical Genetics (ACMG) Standards and Guidelines for Clinical Genetics Laboratories. While these requirements are intended to provide the highest level of assurance that a single laboratory can offer, the ideal practice to assure the accuracy of prenatal diagnosis testing is through duplicate testing conducted by independent laboratories. We recommend that referring medical professionals make the necessary arrangements for these two independent analyses for their patients prior to performing the prenatal diagnostic procedure.

Physician/Counselor Acknowledgement: _____

PRENATAL TESTING OPTIONS

IMPORTANT INSTRUCTIONS FOR CMA and/or FETAL MOLECULAR STUDIES: Parental and familial samples (draw 5-7cc in an EDTA purple-top tube, or buccal swab) required for control and MCC studies. Label with name, DOB, and complete the Parental and Familial Samples section above.

CONCURRENT STUDIES

(Please see reflex column if studies should be done reflexively)

	AF	CVS	Blood	Tissue/POC
AFAFP + AChE*	☐ 8550			
AFAFP*	☐ 8501			
Aneuploidy FISH (For 13, 18, 21, X and Y; chromosomes or CMA must also be ordered)	☐ 8410	☐ 8410		
Rapid FISH (13, 18, 21, X, Y)			☐ 8425	
Chromosome Analysis	☐ 8530	☐ 8700	☐ 8600	☐ 8800
CMA Comprehensive			☐ 8665	☐ 8639
Expanded CMA	☐ 8670	☐ 8671		
Expanded CMA + Limited Chromosome Analysis	☐ 8675	☐ 8676		
Targeted CMA	☐ 8656	☐ 8657		
Targeted CMA + Limited Chromosome Analysis	☐ 8673	☐ 8672		
Prenatal Noonan	☐ BG-24001-P12-5	☐ BG-24001-P12-5		

* AF-AFP and AChE performed at Integrated Genetics
** Additional charges will apply, TAT commences from date reflex order is added

Note: Extracted DNA samples are not accepted for CMA + Limited Chromosome Analysis.

REFLEX STUDIES

(Please see concurrent testing column for additional orders)

- ☐ Chromosome Analysis - If chromosomes are normal, add: **
  - ◯ Expanded CMA ◯ Targeted CMA
- ☐ Aneuploidy FISH and Chromosome Analysis - If FISH is normal, add: **
  - ◯ Expanded CMA ◯ Targeted CMA
- ☐ Aneuploidy FISH and Chromosome Analysis - If chromosomes are normal, add: **
  - ◯ Expanded CMA ◯ Targeted CMA
- ☐ Hold Cells for Potential Add-On Testing

Please specify potential add-on test(s) below:

_____

FETAL VIRAL STUDIES SENDOUT (AMNIOTIC FLUID ONLY)

- ☐ 8940 Herpes Simplex Virus, 1 & 2
- ☐ 8945 Cytomegalovirus (CMV)
- ☐ 8950 Toxoplasma (TOXO) gondii
- ☐ 8955 Parvovirus (PARVO) B19

PHYSICIAN NOTES

Additional testing information and requisitions are available at www.baylorgenetics.com.

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INFORMED CONSENT FOR PRENATAL TESTING

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 prenatal genetic testing, which you should discuss with your healthcare provider or a genetic counselor. To assist you in understanding the purpose, risks, benefits, and limitations of this testing, we have provided information about the testing process and potential results below.

The purpose of prenatal genetic testing is to predict if a patient's pregnancy has a genetic disease or is at an increased risk to develop a genetic disease. 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 changes (also called mutations or variants) in a pregnancy that might cause disease or make it more likely to develop disease. Prenatal testing is typically performed if there is a known family history of a genetic disease and/or other clinical findings are identified about a pregnancy that are suggestive of a genetic disease. Once the results of testing become available, you should discuss the significance of these results with your healthcare provider or genetic counselor.

For the purposes of this consent, prenatal genetic testing might be performed on a single fetus or multiple fetuses of the same pregnancy (e.g., twin gestation)

Depending on the reason genetic testing is offered, your pregnancy 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 may be performed. Each test may be used to identify different variants or diseases.

RESULTS

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

- **Positive:** Positive, "abnormal", or "detected" results mean there is a change in the DNA of the pregnancy that is predicted to cause a genetic disease and/or that the pregnancy is at an increased risk of developing a disease in the future. It is possible for a pregnancy 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, "normal", or "not detected" results mean the DNA of the pregnancy was not identified to have changes associated with a genetic disease. This might indicate that there are no variants associated with disease in the DNA tested. Genetic testing, while highly accurate, might not detect a variant present in the DNA 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 Clinical Significance:** Testing can detect variant(s) in DNA which we do not yet fully understand. These are also referred to as variants of uncertain clinical significance (VUS). Additional testing may be recommended for your pregnancy if a VUS is identified.
- **Secondary / Incidental Findings:** Testing can sometimes detect a variant in the 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 can be used for most types of prenatal testing. If prenatal Huntington disease (HD) testing or whole exome sequencing (WES) is needed, there is a separate consent form for these tests. Consent forms for other tests are located at Baylor Genetics' website (https://www.baylorgenetics.com/consent/).
- Results may indicate your pregnancy has a genetic disease or is at increased risk to develop a genetic disease.
- It is important to understand that genetic tests, even if negative, cannot rule out every variant or every condition. It is not possible to exclude risks for all genetic diseases for your pregnancy.
- It is possible that even if the test identifies the underlying genetic cause for clinical findings in your pregnancy this information may not help in predicting the severity or progression of disease or change management or treatment of disease.
- 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 pregnancy developing the disease or the severity of the disease. This additional testing might need to be performed on your pregnancy or other members of your family and will be discussed by your health care provider.
- 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 for other reasons. In these cases, another sample may need to be sent to the laboratory to perform the testing.
- Parental samples are highly recommended when prenatal genetic testing is performed. They are used as control samples to ensure accurate prenatal results are issued.

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INFORMED CONSENT FOR PRENATAL TESTING

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

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 among 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.
- 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 been received by Baylor Genetics. 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 my test results directly from Baylor Genetics by providing a written request. I also understand that laboratory raw data 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 heath care providers unless specific prior arrangements have been made.
- 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.
- Samples from residents of New York State will not be included in general research studies without your written consent and will not be retained for more than 60 days after receipt of the sample, unless specifically authorized by your selection below. No tests other than those authorized shall be performed on the biological sample.

FOR SAMPLES SUBMITTED FROM NEW YORK STATE

_____ (Initial) I understand that no genetic test other than those I have authorized shall be performed on my biological sample, and the sample will be destroyed at the end of testing or not more than 60 days after the sample was taken. However, by initialing here, I hereby authorize the lab to retain my sample(s) for longer retention in accordance with the laboratory retention policy for internal laboratory quality assurance studies and possible research testing.

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.

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/.

I understand that a completed Advance Beneficiary Notice (ABN) is required for Medicare fee for service patients if the service is not payable by Medicare as not medically necessary or reasonable.

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 via secure email will be made if an email address is provided):

☐ Email ☐ Phone ☐ Mail

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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 prenatal genetic testing as ordered by my physician.

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

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

_____ Relationship of Personal Representative* to the Patient

_____ Paternal Name
_____ Paternal Signature
_____ / _____ / _____ Date Signed (MM / DD / YYYY)

_____ Paternal Personal Representative* Name
_____ Paternal Personal Representative Signature
_____ / _____ / _____ Date Signed (MM / DD / YYYY)

_____ Relationship of Paternal Personal Representative

_____ Ordering Provider's Signature
_____ / _____ / _____ Date Signed (MM / DD / YYYY)

FOR SURROGATE PREGNANCIES

Maternal cell contamination (MCC) studies are performed using a sample of blood or buccal cells from a pregnant person. MCC studies are used to exclude the presence of any DNA from the pregnant person in the fetal DNA sample. The results of MCC studies are not used for the treatment or management of the fetus, pregnant person or gamete (egg/sperm) donor, and the data generated are not part of the pregnant person's designated record.

I hereby give permission for my sample to be used for MCC studies:

_____ Surrogate Printed Name
_____ Surrogate 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, you may be required to provide evidence of your authority.