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

TUMOR ANALYSIS REQUISITION

PATIENT INFORMATION (COMPLETE ONE FORM FOR EACH PERSON TESTED)

Patient Last Name | Patient First Name | MI | Date of Birth (MM / DD / YYYY)

Address | City | State | ZIP Code

Phone | Accession # | Hospital / Medical Record # | Patient discharged from the hospital/facility: ◯ Yes ◯ No

Genetic Sex: ◯ Female ◯ Male ◯ Unknown Gender identity (if different from left):

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

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 / Guardian Printed Name | Patient / Guardian 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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TUMOR ANALYSIS REQUISITION

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 INFORMATION

Date of Collection (MM / DD / YYYY) | Time of Collection

NOTE: Extracted DNA/RNA will only be accepted if the isolation of nucleic acids for clinical testing occurs in a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by the CAP and/or the CMS.

REQUIRED FOR BREAST CANCER FFPE SAMPLES

Method of Fixation | Time to Tissue Fixation | Tissue Fixation Time

SAMPLE TYPE (PLEASE REFER TO PAGE 5 FOR SAMPLE REQUIREMENTS)

- ◯ Blood in EDTA Tube (Purple-Top) +
- ◯ Blood in Sodium Heparin (Green-Top) +
- ◯ Bone Marrow in Sodium Heparin (Green-Top) +
- ◯ Bone Marrow in EDTA (Purple-Top) +
- ◯ FFPE - Slides * #: _____
- ◯ FFPE - Tissue Block *
- ◯ Fresh Frozen Tissue ± *
- ◯ Tissue in Medium ± *
- ◯ DNA (Concentration) + ± *: _____
- ◯ RNA (Concentration) + ± *: _____
- ◯ Other **: _____

\+ For hematologic samples, attach clinical notes and concurrent laboratory reports (such as CBC, flow cytometry, cytogenetics, FISH, molecular testing, and pathology reports). Concurrent laboratory reports may be sent later as soon as available.

* Surgical Pathology report MUST be attached for all tissue samples but may be sent later as soon as it becomes available.

** Please call for consultation before ordering test.

± Please send a corresponding representative H+E slide, if available.

Biological Sex of Bone Marrow Transplant Donor (select one): ◯ Female ◯ Male

INDICATION FOR TESTING (REQUIRED)

Indication(s) | ICD10 Diagnosis Code(s)

RETURN OF FFPE SPECIMENS

☐ Check if block and/or H&E stained slide should be returned. Fill out the return address information below, or affix preprinted label.

This section will be used as the return address label.

Institution | ATTN

Address

City | State | ZIP

SPECIMEN RETRIEVAL

☐ I want Baylor Genetics to request the specimen. (Complete information below)

Location of Specimen

Contact Name

Phone # | Fax #

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TUMOR ANALYSIS REQUISITION

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

BH = Blood in Sodium Heparin (green-top) **BMH** = Bone Marrow in Sodium Heparin (green-top) **BE** = Blood in EDTA (purple-top) **BME** = Bone Marrow in EDTA (purple-top)
TM = Tissue in Medium **FFPE** = Slides/Block **FFPE** = Slides/Block **T** = Fresh Frozen Tissue

CANCER MOLECULAR ANALYSIS

SINGLE GENE TESTING

	TEST CODE	TEST NAME	SAMPLE TYPE
☐	9202	B-Cell Clonality Screening (IgH and IgK) by PCR	BE, BME, FFPE, T
☐	9065	BCR-ABL1, Major (p210), Quantitative	BE, BME
☐	8972	BCR-ABL1, Minor (p190), Quantitative	BE, BME
☐	9070	BCR-ABL1, Qualitative Analysis w/ Reflex to BCR-ABL1 Quantitative [4]	BE, BME
☐	9305	BCR-ABL1 Mutation Analysis for Tyrosine Kinase Inhibitor Resistance by NGS	BE, BME
☐	9003	BRAF V600 Mutation Analysis	BE, BME, FFPE
☐	9016	CALR (Calreticulin) Exon 9 Mutation Analysis by PCR	BE, BME
☐	9086	CEBPA Mutation Detection	BE, BME
☐	9030	EGFR Mutation Detection by Pyrosequencing	FFPE
☐	9045	FLT3 Mutation Detection by PCR [2]	BE, BME
☐	9104	Gastrointestinal Stromal Tumor Mutation (KIT, PDGFRA)	FFPE
☐	9060	IGHV Mutation Analysis by Sequencing	BE, BME
☐	9015	JAK2 Exon 12 Mutation Analysis by PCR	BE, BME
☐	9010	JAK2 Gene, V617F Mutation, Qualitative	BE, BME
☐	8970	KIT (D816V) Mutation by PCR	BE, BME
☐	9103	KIT Mutations, Melanoma (including PDGFRA)	FFPE
☐	9105	KIT Mutations in AML by Fragment Analysis and Sequencing	BE, BME
☐	9128	KRAS Mutation Detection	FFPE
☐	8974	MGMT Methylation Detection by PCR	FFPE
☐	9150	Microsatellite Instability (MSI), HNPCC/Lynch Syndrome, by PCR [3]	FFPE
☐	9020	MPL Codon 515 Mutation Detection by Pyrosequencing, Quantitative	BE, BME
☐	8973	MYD88 L265P Mutation Detection by PCR, Quantitative	BE, BME, FFPE
☐	9005	NPM1 Mutation Detection by RT-PCR, Quantitative	BE, BME
☐	8971	NRAS Mutation Detection by Pyrosequencing	FFPE
☐	8976	PD-L1 28-8 pharmDx by Immunohistochemistry with Interpretation, nivolumab (OPDIVO)	FFPE
☐	8975	PD-L1 22C3 IHC for NSCLC by Immunohistochemistry with Interpretation, pembrolizumab (KEYTRUDA)	FFPE
☐	8977	PD-L1 22C3 IHC with Combined Positive Score (CPS) Interpretation, pembrolizumab (KEYTRUDA)	FFPE
☐	9080	PML-RARA Translocation, t(15;17) by RT-PCR, Quantitative	BE, BME
☐	9217	T-Cell Clonality Screening by PCR	BE, BME, FFPE, T
☐	9055	TP53 Somatic Mutation, Prognostic	BE, BME, FFPE

REFLEX TESTS

Reflex Request (Please describe below):

[1] For test code 9505: If sending FFPE slides, 20 slides are required for submission.
[2] For test code 9045: Test will be sent to LabPMM for analysis and reporting.
[3] For test code 9150: Please submit BOTH a source of tumor tissue (FFPE block/slides) AND a source of normal tissue (FFPE block/slides).
[4] For test code 9070: If BCR-ABL1, Major (p210) is detected, reflex to 9065, and if BCR-ABL1, Minor (p190) is detected, reflex to 8972.

CYTOGENETIC TESTS

SINGLE FISH PROBES

	TEST CODE	TEST NAME	SAMPLE TYPE
☐	8030	ALK Rearrangement	FFPE
☐	8725	AML1/ETO: t(8;21) [AML]	BH, BMH
☐	8785	BCL2 Rearrangement	FFPE
☐	8775	BCL6 Rearrangement	BH, BMH, FFPE
☐	8750	BCR/ABL: t(9;22) [CML/ALL/AML]	BH, BMH
☐	8740	CBFB: inv(16) [AML]	BH, BMH
☐	8730	CHIC2: Deleted 4q [Hypereosinophilic Syndrome]	BH, BMH
☐	8710	Deletion 5: [MDS]	BH, BMH
☐	8715	Deletion 7: [MDS]	BH, BMH
☐	8720	Deletion 20q12: [MDS]	BH, BMH
☐	8065	DXZ1/DYZ3	BH, BMH
☐	8035	EGFR	FFPE
☐	8385	Gain Chromosome 8	BH, BMH
☐	8780	IGH Rearrangement	BH, BMH
☐	8770	IGH/CCND1: t(11;14) [Mantle Cell Lymphoma]	BH, BMH, FFPE
☐	8795	IGH/MYC Analysis	FFPE
☐	8786	MALT1 Lymphoma	BH, BMH
☐	8705	MECOM (EVI1) Analysis	BH, BMH
☐	8095	MET Amplification	FFPE
☐	8745	MLL: 11q23	BH, BMH
☐	8760	MYC translocation	BH, BMH, FFPE
☐	8788	p53	BH, BMH
☐	8735	PML/RARA: t(15;17) [AML]	BH, BMH
☐	8031	RET Rearrangement	FFPE
☐	8781	ROS1 Rearrangement	FFPE
☐	8075	SS18 [Synovial Sarcoma]	FFPE
☐	8080	TCF3/PBX1 [ALL]	BH, BMH
☐	8755	TEL/AML1: t(12;21) [ALL]	BH, BMH
☐	8400	OTHER, Probe Name:	

CLASSICAL CHROMOSOME ANALYSIS

	TEST CODE	TEST NAME	SAMPLE TYPE
☐	8300	Hematologic Cancer	BH, BMH
☐	8050	Solid Tumor	TM

FISH PANELS

	TEST CODE	TEST NAME	SAMPLE TYPE
☐	8789	Aggressive/High-Grade B-Cell Lymphoma (MYC translocation, BCL2 rearrangement, BCL6 rearrangement)	FFPE
☐	8010	ALL Adult (CDKN2A del, BCR/ABL gene fusion, KMT2A rearrangement, IGH rearrangement, Trisomy 4, Trisomy 10) ☐ If the result is negative, reflex to 8012	BH, BMH
☐	8012	ALL Ph-Like FISH Panel (PDGFRb, BCR/ABL1-ASS1, JAK2, EPOR, CRLF2)	BH, BMH
☐	8792	ALL Pediatric (BCR/ABL translocation, KMT2A rearrangement, ETV6/RUNX1 translocation, Trisomy 4, Trisomy 10, TCF3/PBX1 amplification/deletion)	BM, BMH
☐	8000	AML (Trisomy 8, AML/ETO, MLL rearrangement, PML/RARA, CBFB inversion)	BH, BMH
☐	8040	CLL (Trisomy 12, ATM del, p53 del, MYB del, 13q del, IGH rearrangement, IGH/CCND1 fusion)	BH, BMH
☐	8791	Eosinophilia (PDGFRB rearrangement, FGFR1 rearrangement, JAK2 rearrangement, PDGFRA/CHIC2/FIP1L1 rearrangement, CBFB rearrangement)	BH, BMH
☐	8005	MDS (5 del, 7 del, Trisomy 8, MLL rearrangement, 20q del)	BH, BMH
☐	8015	Multiple Myeloma (Trisomy 9, RB1 del, IGH rearrangement, Trisomy 15, p53 del, Trisomy 7, CKS1B/CDKN2C amplification/deletion) ☐ If IGH rearrangement positive, reflex to 8790	BH, BMH
☐	8790	Multiple Myeloma IgH Rearrangement (IGH/MAF fusion, IGH/FGFR3 fusion, IGH/CCND1 fusion)	BH, BMH
☐	8020	NHL (BCL6 rearrangement, IGH/CCND1 fusion, MYC rearrangement, MALT1 rearrangement, BCL2 rearrangement)	BH, BMH
☐	8787	Non-Small Cell Lung Carcinoma (ALK rearrangement, MET amplification, RET rearrangement, ROS1 rearrangement)	FFPE
☐	8793	NTRK (NTRK1 rearrangement, NTRK2 rearrangement, NTRK3 rearrangement)	FFPE

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TUMOR ANALYSIS REQUISITION

SAMPLE SPECIFICATIONS TABLE

FOR CLIENT INFORMATION ONLY. Not required with sample submission.

ABBREVIATION	SAMPLE NAME	RECOMMENDED AMOUNT		SHIPPING INSTRUCTIONS	SPECIAL NOTES
		(2 YRS - ADULT)	(NEWBORN - 2YRS)		
BE	Blood in EDTA tube (purple-top)	3 - 5 cc	2 -3 cc	Ship at room or refrigerated temperature in an insulated container by overnight courier. Do not heat or freeze. Specimen should arrive in the laboratory within 24-48 hours of collection.	Attach clinical notes and concurrent laboratory reports (such as CBC, flow cytometry, cytogenetics, FISH, molecular testing, and pathology reports). Concurrent laboratory results may be sent later as soon as available.
BH	Blood in Sodium Heparin tube (green-top)	3 - 5 cc	2 -3 cc	Ship at room or refrigerated temperature in an insulated container by overnight courier. Do not heat or freeze. Specimen should arrive in the laboratory within 24-48 hours of collection.	Attach clinical notes and concurrent laboratory reports (such as CBC, flow cytometry, cytogenetics, FISH, molecular testing, and pathology reports). Concurrent laboratory results may be sent later as soon as available.
BME	Bone Marrow in EDTA tube (purple-top)	3 - 5 cc	2 -3 cc	Ship at room or refrigerated temperature in an insulated container by overnight courier. Do not heat or freeze. Specimen should arrive in the laboratory within 24-48 hours of collection.	Attach clinical notes and concurrent laboratory reports (such as CBC, flow cytometry, cytogenetics, FISH, molecular testing, and pathology reports). Concurrent laboratory results may be sent later as soon as available.
BMH	Bone Marrow in Sodium Heparin tube (green-top)	3 - 5 cc	2 -3 cc	Ship at room or refrigerated temperature in an insulated container by overnight courier. Do not heat or freeze. Specimen should arrive in the laboratory within 24-48 hours of collection.	Attach clinical notes and concurrent laboratory reports (such as CBC, flow cytometry, cytogenetics, FISH, molecular testing, and pathology reports). Concurrent laboratory results may be sent later as soon as available.
DNA	DNA, Extracted	At Least 100 ng	At Least 100 ng	Ship at room or refrigerated temperature in an insulated container by overnight courier. May also be shipped frozen on minimum of 10 lbs of dry ice in an insulated container by overnight courier.	Minimum concentration of 25ng/uL. Attach clinical notes, concurrent laboratory reports, and/or surgical pathology report, as applicable. Please send a corresponding representative H+E slide, if available.
FFPE	FFPE - Block	See Special Notes	See Special Notes	Ship at room temperature in an insulated container by overnight courier. If shipping during the summer months please include a cold-pack to avoid extreme temperatures. Do not heat or freeze.	Paraffin-embedded, formalin-fixed tissue block containing ≥20% tumor nuclei with a minimum tumor surface area of 5mm x 5mm ($25mm^2$). Decalcified specimens are not accepted. Surgical pathology report must be attached for all tissue samples.
FFPE	FFPE - Slides	See Special Notes	See Special Notes	Ship at room temperature in an insulated container by overnight courier. If shipping during the summer months please include a cold-pack to avoid extreme temperatures. Do not heat or freeze.	10 - 15 unstained 5µm FFPE slides containing ≥20% tumor nuclei with a minimum tumor surface area of 5mm x 5mm ($25mm^2$). For smaller specimens, 20 or more unstained 5µm FFPE slides containing ≥20% tumor nuclei should be submitted. Decalcified specimens are not accepted. Surgical pathology report must be attached for all tissue samples. For test codes 9505: 20 slides are required for submission.
RNA	RNA, Extracted	At Least 100 ng	At Least 100 ng	Ship frozen on minimum of 10 lbs of dry ice in an insulated container by overnight courier.	Minimum concentration of 25ng/uL. Attach clinical notes, concurrent laboratory reports, and/or surgical pathology report, as applicable. Please send a corresponding representative H+E slide, if available.
SA	Saliva	See Special Notes	See Special Notes	Ship at room temperature in an insulated container by overnight courier. Do not heat or freeze.	Collected with Oragene DNA Self-Collection Kit (provided by Baylor Genetics with instructions).
T	Fresh Frozen Tissue	150 mg	150 mg	Ship frozen on minimum of 10 lbs of dry ice in an insulated container by overnight courier.	Fresh tissue snap frozen at ≤-20°C. Store at ≤-20°C. Surgical pathology report must be attached for all tissue samples. Surgical pathology report may be sent later as soon as it becomes available. Please send a corresponding representative H+E slide, if available.
TM	Fresh Tissue in Medium	0.5 - 1 cm^3 or more	0.5 - 1 cm^3 or more	Ship at room or refrigerated temperature in an insulated container by overnight courier. Do not heat or freeze. Specimen should arrive in the laboratory within 48 hours of collection.	Transport tumor tissue in a sterile, screw-top container filled with tissue culture transport medium. If tissue culture transport medium is not available, collect in plain RPMI, Hanks solution, or saline. Surgical pathology report must be attached for all tissue samples. Surgical pathology report may be sent later as soon as it becomes available. Please send a corresponding representative H+E slide, if available.

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INFORMED CONSENT FOR TUMOR ANALYSIS TESTING

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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INFORMED CONSENT FOR TUMOR ANALYSIS TESTING

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

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 heath 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

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1.800.434.9850

CONNECT

INFORMED CONSENT FOR TUMOR ANALYSIS TESTING

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.