Test Requisition for Tissue Culturing (Oncology)

COMPLETE ENTIRE FORM TO AVOID DELAYS

Baylor Genetics
2450 Holcombe Blvd, Houston, TX 77021-2024 | CLIA# 45D0660090

PATIENT INFORMATION

Legal Name (Last, First, MI)	Date of Birth (MM/DD/YY)	Sex Assigned at Birth ☐F ☐M	Gender (optional) ☐Man ☐Woman ☐Nonbinary ☐Self-described

Genetic Ancestry: ☐Ashkenazi Jewish ☐Asian ☐Black/African American ☐French Canadian/Cajun ☐Hispanic/Latino ☐Mediterranean ☐Middle Eastern ☐Native American ☐Pacific Islander ☐Portuguese ☐White ☐Unknown ☐Other: | MRN

Address	City	State	Zip

Mobile #	Email	Preferred Billing ☐Insurance ☐Self-pay ☐Institutional

SPECIMEN TRANSPORT ☑ Room Temperature

Collection Date (MM/DD/YY): _____ Time: _____ ☐AM ☐PM
Collection date is required for testing to proceed. Failure to provide may result in delays and/or test cancellation.

Number of Specimens Submitted: _____

Specimen Details: Tissue Type (*e.g.* skin): _____ Site (*e.g.* left arm): _____ Sample Type (*e.g.* punch biopsy): _____

Testing laboratory handling instructions: Sample will be cultured at Baylor Genetics; 2 (two) T-25 flasks will be sent to Ambry Genetics for testing. Sample will not be frozen for long-term storage.

FedEx tracking number: Comments and Special Instructions:

ORDERING PHYSICIAN OR OTHER LICENSED MEDICAL PROFESSIONAL Facility Type: ☐Physician/Physician Group ☐Referral Lab

Name (Last, First, Degree)	Facility Name	NPI#	
Kit Shipment Street Address	City	State	Zip
Phone	Fax	E-mail	

ADDITIONAL RESULTS RECIPIENTS

Genetic Counselor or Other Medical Provider Name (Last, First) (Code) Phone/Fax/Email

PATIENT CLINICAL HISTORY

	Describe (attach clinical notes, family notes)		
Personal History of Cancer ☐Yes ☐No	Age of Dx	Diagnosis Notes (cancer type, etc.)	ICD-10 Code(s)
Family History of Cancer ☐Yes ☐No	Family History Details		
Prior Genetic Testing ☐Yes ☐No	Patient	Family	

5. TEST ORDERS

Order Code: 8814 Tissue Culture Baylor Genetics (AG: 7030) ☑ Grow and Send Ambry Billing ID: AGAC

! REQUIRED: Select a Primary Test Order

For Patients Meeting *BRCA1/2* Testing Criteria

☐ *BRCA1/2* test

For Patients Meeting Colorectal Cancer Syndrome Testing Criteria (Lynch)

Lynch Syndrome test: ☐ *MLH1, MSH2, MSH6, PMS2, EPCAM*

For Patients Meeting Colorectal Cancer Syndrome Testing Criteria (polyposis)

Polyposis test: ☐ *APC/MUTYH*

☐ Other: _____
☐ None of the above (patient does not meet any genetic testing criteria)

Select an Optional Supplemental Test (Per payer policy, all tests in this section will be processed and billed separately; tests may be performed as a reflex.)

☐ CancerNext® (8824)
☐ BRCAplus® (8836)
☐ BRCANext® (8857)
Add on: ☐ Limited Evidence
☐ ColoNext® (8821)
Add on: ☐ Limited Evidence

☐ CancerNext-*Expanded*® (8875)
Add on: ☐ Limited Evidence ☐ Pancreatitis
☐ CustomNext-*Cancer*® (9511)
Notes: _____
☐ Specific Site Analysis (5555): Proband report is required.
Gene_____ Variant (c./p.):_____
☐ Other: _____

Other Supplemental Test Options (Select if applicable)

☐ +RNAinsight® (Not available with BRCAplus or STAT orders; PAXgene® tube required for RNA)

Will the course of treatment change depending upon the results of the test? ☐ Yes ☐ No

STAT TEST: ☐ Date results needed (if known): _____

Was genetic counseling completed? ☐ Yes ☐ No ☐ Unknown Date Genetic Counseling was Performed: _____

Patient Signature (I agree to terms below): Date:

Medical Professional Signature (I agree to terms below): Date:

TERMS AND CONDITIONS

Patient Acknowledgement: I acknowledge that the information provided by me is true and correct. For direct insurance billing: I authorize my insurance benefits to be paid directly to Ambry Genetics Corporation (Ambry), authorize Ambry to release medical information concerning my testing to my insurer, to be my designated representative for purposes of appealing any denial of benefits as needed and to request additional medical records for this purpose. I understand that I am responsible for sending Ambry money received from my health insurance company.

For NY residents: ☐ By checking this box, I agree that Ambry Genetics will retain my sample for 6 months after the testing above has been completed. By not checking this box, I understand that under New York State law, Ambry Genetics must discard my sample after the longer of (a) testing completion and (b) 60 days after the Date of Collection above.

Medical Professional: Confirmation of Informed Consent, Pre-test Genetic Counseling, and Medical Necessity for Genetic Testing
The undersigned person (or representative thereof) ensures he/she is a licensed medical professional authorized to order genetic testing and confirms that the patient has given appropriate consent. I confirm that testing is medically necessary and that test results may impact medical management for the patient. I agree to allow Ambry Genetics to facilitate the provision of pre-test genetic counseling services by a third-party service, as required by the patient's insurance provider. Furthermore, all information on this TRF is true to the best of my knowledge. My signature applies to the attached letter of medical necessity.

Ambry Genetics | BAYLOR GENETICS

Patient Name: _____ DOB: _____

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INSTRUCTIONS FOR SUBMITTING SAMPLE TO BAYLOR GENETICS :

KIT REQUEST

1. 7-10 days prior to patient's procedure, please place an order for a Baylor Genetics' CVS Transport Media Kit through their website at baylorgenetics.com/supplies.
2. On step 3 select "custom options". On step 4 enter TC 8814 at the top and enter the desired qty of **15ml Conical Tube(s) CVS Transport Media**.
3. For any questions, please contact Baylor Genetics' Client Services at 1-800-411-4363 or email help@baylorgenetics.com.
4. Upon receipt of the online kit request, Baylor Genetics will ship a CVS Transport Media Kit to the requested address, which should arrive within 3-5 business days. For urgent kit requests, expedited shipping options are available.

PREPARING SAMPLE

Upon receiving the kit, place tube with media in the refrigerator until ready for use.

Specimen preparation: Collect 5 cubic millimeters of skin from a central location (*e.g.* buttock or upper thigh) rather than from a distal location (*e.g.* foot) to enhance cell viability. Place sample in a separate sterile container with RPMI media (included in the Baylor Genetics' CVS Transport Media Kit). In the absence of RPMI media, place sample along with a small amount of sterile saline in a sterile container with a cap that can be tightened to prevent leakage. Never place samples in formalin or other fixative.

Storage/transport temperature: Ship at room temperature in an insulated container by overnight courier. Do NOT heat or freeze.

Stability: Sample must arrive at culture lab within 48 hrs. of collection.

For questions related to tissue culturing, please contact Baylor Genetics' Client Services at 1-800-411-4363 or email help@baylorgenetics.com.

SHIPPING

1. Include completed Test Requisition Form with the CVS Transport Media Kit and provide FedEx tracking number.
2. Fax (949-900-5501) or email (CulturedSamples@ambrygen.com) completed Test Requisition Form to Ambry Genetics.
3. Ship sample to Baylor Genetics at 2450 Holcombe Blvd, Grand Blvd. Receiving Dock, Houston, TX 77021-2024.

Please note that fibroblast cultures typically take 2-3 weeks to complete.

If multiple skin biopsy specimens are collected, only one biopsy specimen will be cultured and sent to Ambry. If you require an exception to the standard specimen processing, please notify Baylor upon sample submission (additional charges may apply). Remaining cultures at Baylor Genetics will be discarded 14 days after sending initial 2 T25s to Ambry, unless additional cultures are requested prior to discard.

For questions related to acceptable specimens, test status, or results, please contact Ambry Genetics at 949-900-5500.

Ambry Genetics®

Patient Name: _____ DOB: _____

Supplemental Information

Hereditary Cancer Multi-Gene Tests

TEST NAME	TEST CODE	GENES
Pan-cancer		
CancerNext® (39 genes)	8824	*APC, ATM, AXIN2, BAP1, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDKN2A, CHEK2, EPCAM, FH, FLCN, GREM1, HOXB13, MBD4, MET, MLH1, MSH2, MSH3, MSH6, MUTYH, NF1, NTHL1, PALB2, PMS2, POLD1, POLE, PTEN, RAD51C, RAD51D, SMAD4, STK11, TP53, TSC1, TSC2, VHL*
CancerNext-*Expanded*® (76 genes or up to 90 genes w/ add-ons)	8875	*AIP, ALK, APC, ATM, AXIN2, BAP1, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1, CDC73, CDH1, CDK4, CDKN1B, CDKN2A, CEBPA, CHEK2, CTNNA1, DDX41, DICER1, EGFR, EPCAM, ETV6, FH, FLCN, GATA2, GREM1, HOXB13, KIT, LZTR1, MAX, MBD4, MEN1, MET, MITF, MLH1, MSH2, MSH3, MSH6, MUTYH, NF1, NF2, NTHL1, PALB2, PDGFRA, PHOX2B, PMS2, POLD1, POLE, POT1, PRKAR1A, PTCH1, PTEN, RAD51C, RAD51D, RB1, RET, RUNX1, SDHA, SDHAF2, SDHB, SDHC, SDHD, SMAD4, SMARCA4, SMARCB1, SMARCE1, STK11, SUFU, TMEM127, TP53, TSC1, TSC2, VHL, WT1* Optional Add-on 1 - Limited Evidence Genes (9 genes): *ATRIP, EGLN1, KIF1B, MLH3, PALLD, RAD51B, RNF43, RPS20, TERT* Optional Add-on 2 - Pancreatitis Genes (5 genes): *CFTR, CPA1, CTRC, PRSS1, SPINK1*
STAT Breast Management		
BRCAPlus® (13 genes)	8836	*ATM, BARD1, BRCA1, BRCA2, CDH1, CHEK2, NF1, PALB2, PTEN, RAD51C, RAD51D, STK11, TP53*
Breast & gynecologic		
BRCANext® (19 genes or up to 26 genes w/ add-on)	8857	*ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, EPCAM, MLH1, MSH2, MSH6, NF1, PALB2, PMS2, PTEN, RAD51C, RAD51D, STK11, TP53* Optional Add-on - Limited Evidence Genes (7 genes): *ATRIP, CDC73, FH, NTHL1, POLD1, POLE, RAD51B*
Colorectal & polyposis		
ColoNext® (20 genes or up to 26 genes w/ add-on)	8821	*APC, AXIN2, BMPR1A, CDH1, EPCAM, GREM1, MBD4, MLH1, MSH2, MSH3, MSH6, MUTYH, NTHL1, PMS2, POLD1, POLE, PTEN, SMAD4, STK11, TP53* Optional Add-on - Limited Evidence Genes (6 genes): *ATM, CHEK2, CTNNA1, MLH3, RNF43, RPS20*
Customizable		
CustomNext-*Cancer*® (up to 90 genes) Required: complete CustomNext-*Cancer* supplemental form. ambrygen.com/forms	9511	To order all genes on Ambry's oncology menu, please order CancerNext-*Expanded*. *AIP, ALK, APC, ATM, ATRIP, AXIN2, BAP1, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1, CDC73, CDH1, CDK4, CDKN1B, CDKN2A, CEBPA, CFTR, CHEK2, CPA1, CTNNA1, CTRC, DICER1, DDX41, EGFR, ELGN1, EPCAM, ETV6, FH, FLCN, GATA2, GREM1, HOXB13, KIF1B, KIT, LZTR1, MAX, MBD4, MEN1, MET, MITF, MLH1, MLH3, MSH2, MSH3, MSH6, MUTYH, NF1, NF2, NTHL1, PALB2, PALLD, PDGFRA, PHOX2B, PMS2, POLD1, POLE, POT1, PRKAR1A, PRSS1, PTCH1, PTEN, RAD51B, RAD51C, RAD51D, RB1, RET, RNF43, RPS20, RUNX1, SDHA, SDHAF2, SDHB, SDHC, SDHD, SMAD4, SMARCA4, SMARCB1, SMARCE1, SPINK1, STK11, SUFU, TERT, TMEM127, TP53, TSC1, TSC2, VHL, WT1* For Medicare Patients: At a minimum, the following core genes must be included in the panel to ensure Medicare coverage: *APC, ATM, BRCA1, BRCA2, CHEK2, EPCAM, MLH1, MSH2, MSH6, PALB2, PMS2, PTEN, TP53.*
Syndrome specific		
Adenomatous polyposis	8726	*APC, MUTYH*
BRCA1/2-associated hereditary breast and ovarian cancer (HBOC)	8838	*BRCA1, BRCA2*
Lynch syndrome	8517	*MLH1, MSH2, MSH6, PMS2 + EPCAM del/dup*

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