

LLUMC Test Requisition for Tissue Culturing (Oncology)



Loma Linda University Medical Center Clinical Lab/Genetics

11223 Campus St. South Dock A Loma Linda, CA 92354 USA | CLIA# 05D0573839

COMPLETE ENTIRE FORM TO AVOID DELAYS

PATIENT INFORMATION					
Last Name		First Name		Middle Initial	DOB (MM/DD/YY)
Street Address		City		State	Zip
Preferred Contact Phone Number	Biological Gender: <input type="checkbox"/> F <input type="checkbox"/> M Gender Identity (if different from marked): _____		Ethnicity: <input type="checkbox"/> African American <input type="checkbox"/> Asian <input type="checkbox"/> Caucasian <input type="checkbox"/> Hispanic <input type="checkbox"/> Jewish (Ashkenazi) <input type="checkbox"/> Portuguese <input type="checkbox"/> Other: _____		
Preferred Billing *Copy of front/back of insurance card required. Please complete Patient Assistance program information below, if applicable. <input type="checkbox"/> Insurance* <input type="checkbox"/> Cash <input type="checkbox"/> Institutional			We will start testing immediately, unless you check the box below. We will attempt to contact you if your estimated out-of-pocket costs are > USD \$100 <input type="checkbox"/> Do not start testing until I approve payment terms regarding estimated out-of-pocket costs		
SPECIMEN TRANSPORT <input type="checkbox"/> Room Temperature					
Collection Date (MM/DD/YY): _____ Time: _____ <input type="checkbox"/> AM <input type="checkbox"/> PM			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 LLUMC/Clinical Lab/Genetics; 2 (two) T-25 flasks will be sent to Ambyr Genetics for testing. Sample will not be frozen for long-term storage.					
Prenatal Specimen Details: Sample Type: <input type="checkbox"/> Amniotic Fluid <input type="checkbox"/> Direct Chorionic Villi <input type="checkbox"/> Fetal Tissue Sample Amount: _____ Gestational Age at Collection: _____					
FedEx tracking number: _____ Comments and Special Instructions: _____					
ORDERING PHYSICIAN OR OTHER LICENSED MEDICAL PROFESSIONAL Facility Type: <input type="checkbox"/> Physician/Physician Group <input type="checkbox"/> 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 <input type="checkbox"/> Yes <input type="checkbox"/> No	Age of Dx	Diagnosis Notes (cancer type, etc.)		ICD-10 Code(s)	
Family History of Cancer <input type="checkbox"/> Yes <input type="checkbox"/> No	Family History Details				
Prior Genetic Testing <input type="checkbox"/> Yes <input type="checkbox"/> No	Patient		Family		
TEST ORDER					
STEP 1: Select the indication for testing: <input type="checkbox"/> Hereditary breast and ovarian cancer ¹ <input type="checkbox"/> Lynch ² <input type="checkbox"/> Hereditary polyposis ³ <input type="checkbox"/> None <input type="checkbox"/> Other: _____			STEP 2: Select desired test: <input type="checkbox"/> BRCAplus 8836 <input type="checkbox"/> BreastNext 8820 <input type="checkbox"/> CancerNext 8824 <input type="checkbox"/> CancerNext-Expanded 8874 <input type="checkbox"/> ColoNext 8822 <input type="checkbox"/> OvaNext 8830 <input type="checkbox"/> ProstateNext 8845 <input type="checkbox"/> CustomNext-Cancer 9510 <input type="checkbox"/> Other: _____		
1. BRCA1/2 2. MLH1, MSH2, MSH6, PMS2, EPCAM 3. APC/MUTYH					
Optional: Add AmbyrScore <input type="checkbox"/> Breast (Additional Supplemental Ordering Form REQUIRED) <input type="checkbox"/> Prostate					
Will patient management be changed depending on the test results? <input type="checkbox"/> Yes <input type="checkbox"/> No STAT TEST: <input type="checkbox"/> Date results needed (if known): _____					
Order Code: 7030 - Tissue Culture (LLUMC/Clinical Lab/Genetics) <input type="checkbox"/> Grow and Send <input type="checkbox"/> Other (Specify): _____					
Patient Signature (I agree to terms below):				Date:	
Required for Processing 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 Ambyr Genetics Corporation (Ambyr), authorize Ambyr 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 financially responsible for any amounts not covered by my insurer and responsible for sending Ambyr money received from my health insurance company.					
Ambyr's Patient Assistance Program, please provide the total annual gross household income: \$ _____ and the number of family members in the household supported by the listed income: _____. I authorize Ambyr Genetics Corporation to verify the above information for the sole purpose of assessing financial need, including the right to seek supporting documentation.					
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 Ambyr Genetics to facilitate the provision of pre-test genetic counseling services by a third party service, Informed DNA (unless otherwise noted), as required by the patient's insurance provider (unless this box is checked <input type="checkbox"/>). Furthermore, all information on this TRF is true to the best of my knowledge. My signature applies to the attached letter of medical necessity.					
<small>*Blood or saliva from patients with active/recent hematological disease will undergo additional review and may not be accepted in some cases. For these, cultured fibroblasts or fresh/fresh frozen normal tissue are preferred. See ambyr.com/specimen-requirements for details.</small>					

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INSTRUCTIONS FOR SUBMITTING SAMPLE TO LLUMC/CLINICAL LAB/GENETICS:

KIT REQUEST

1. 7-10 days prior to patient's procedure, please fax completed form to LLUMC/Clinical Lab/Genetics at (909) 558-5946 or call LLUMC/Clinical Lab/Genetics at (909) 558-4000 option 2, ext. 46161.
2. Upon receipt of the completed form, LLUMC/Clinical Lab/Genetics will ship a Tissue Culture Transport/Shipment Kit to the requested address, which should arrive within 3-5 business days.

Please contact LLUMC/Clinical Lab/Genetics at the above number for urgent kit requests

PREPARING SAMPLE

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

Specimen preparation: DO NOT FREEZE. Do not place in formalin. Transport a 4mm sample (e.g. skin punch biopsy) in the sterile, screw-top blue cap tube filled with tissue-transport medium.

Storage/transport temperature: room temperature.

Stability: 48 hrs ambient/refrigerated. Ship sample immediately upon collection. If specimen is ambient for more than 48 hours, specimen may be compromised. The laboratory will make every attempt to culture the specimen.

SHIPPING

1. Include completed Test Requisition form with the Tissue Culture Transport/Shipment 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 LLUMC/Clinical Lab/Genetics at 11223 Campus St. South Dock A Loma Linda, CA 92354

Please note that fibroblast cultures typically take 2-3 weeks to complete. For questions, please contact LLUMC/Clinical Lab/Genetics at (909) 558-4000 option 2, ext. 46161.

Supplemental Information

Hereditary Cancer Multi-Gene Tests

Test Name	Test Code	Genes
Adenomatous polyposis	8726	<i>APC, MUTYH</i>
BrainTumorNext (27 genes)	8847	<i>AIP, ALK, APC, CDKN1B, CDKN2A, DICER1, MEN1, MLH1, MSH2, MSH6, NBN, NF1, NF2, PHOX2B, PMS2, POT1, PRKAR1A, PTCH1, PTEN, SMARCA4, SMARCB1, SMARCE1, SUFU, TP53, TSC1, TSC2, VHL</i>
BRCAplus (8 genes)	8836	<i>ATM, BRCA1, BRCA2, CDH1, CHEK2, PALB2, PTEN, TP53</i>
BreastNext* (17 genes)	8820	<i>ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, MRE11A, MUTYH, NBN, NF1, PALB2, PTEN, RAD50, RAD51C, RAD51D, TP53</i>
CancerNext*^ (34 genes)	8824	<i>APC, ATM, BARD1, BRCA1, BRCA2, BRIP1, BMPR1A, CDH1, CDK4, CDKN2A, CHEK2, DICER1, EPCAM, GREM1, HOXB13, MLH1, MRE11A, MSH2, MSH6, MUTYH, NBN, NF1, PALB2, PMS2, POLD1, POLE, PTEN, RAD50, RAD51C, RAD51D, SMAD4, SMARCA4, STK11, TP53</i>
CancerNext-Expanded*^ (67 genes)	8874	<i>AIP, ALK, APC, ATM, BAP1, BARD1, BLM, BRCA1, BRCA2, BRIP1, BMPR1A, CDH1, CDK4, CDKN1B, CDKN2A, CHEK2, DICER1, EPCAM, FANCC, FH, FLCN, GALNT12, GREM1, HOXB13, MAX, MEN1, MET, MITF, MLH1, MRE11A, MSH2, MSH6, MUTYH, NBN, NF1, NF2, PALB2, PHOX2B, POT1, PMS2, POLD1, POLE, PRKAR1A, PTCH1, PTEN, RAD50, RAD51C, RAD51D, RB1, RET, SDHA, SDHAF2, SDHB, SDHC, SDHD, SMAD4, SMARCA4, SMARCB1, SMARCE1, STK11, SUFU, TMEM127, TP53, TSC1, TSC2, VHL, XRCC2</i>
ColoNext (17 genes)	8822	<i>APC, BMPR1A, CDH1, CHEK2, EPCAM, GREM1, MLH1, MSH2, MSH6, MUTYH, PMS2, POLD1, POLE, PTEN, SMAD4, STK11, TP53</i>
CustomNext-Cancer*^ (up to 81 genes) Required: complete CustomNext-Cancer supplemental form. ambrygen.com/forms	9510	<i>AIP, ALK, APC, ATM, AXIN2, BAP1, BARD1, BLM, BRCA1, BRCA2, BRIP1, BMPR1A, CASR, CDC73, CDH1, CDK4, CDKN1B, CDKN2A, CFTR, CHEK2, CPA1, CTNNA1, CTRC, DICER1, EGFR, EPCAM, FANCC, FH, FLCN, GALNT12, GREM1, HOXB13, KIT, MAX, MEN1, MET, MITF, MLH1, MRE11A, MSH2, MSH3, MSH6, MUTYH, NBN, NF1, NF2, NTHL1, PALB2, PDGFRA, PHOX2B, POT1, PMS2, POLD1, POLE, PRKAR1A, PRSS1, PTCH1, PTEN, RAD50, RAD51C, RAD51D, RB1, RET, SDHA, SDHAF2, SDHB, SDHC, SDHD, SMAD4, SMARCA4, SMARCB1, SMARCE1, SPINK1, STK11, SUFU, TMEM127, TP53, TSC1, TSC2, VHL, XRCC2</i>
GYNplus (13 genes)	8835	<i>BRCA1, BRCA2, BRIP1, EPCAM, MLH1, MSH2, MSH6, PALB2, PMS2, PTEN, RAD51C, RAD51D, TP53</i>
HBOC	8838	<i>BRCA1, BRCA2</i>
Lynch syndrome/HNPCC	8517	<i>MLH1, MSH2, MSH6, PMS2 + EPCAM del/dup</i>
MelanomaNext (8 genes)	8849	<i>BAP1, BRCA2, CDK4, CDKN2A, MITF, PTEN, RB1, TP53</i>
OvaNext* (25 genes)	8830	<i>ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, DICER1, EPCAM, MLH1, MRE11A, MSH2, MSH6, MUTYH, NBN, NF1, PALB2, PMS2, PTEN, RAD50, RAD51C, RAD51D, SMARCA4, STK11, TP53</i>
PancNext (13 genes)	8042	<i>APC, ATM, BRCA1, BRCA2, CDKN2A, EPCAM, MLH1, MSH2, MSH6, PALB2, PMS2, STK11, TP53</i>
Pancreatitis panel (6 genes)	8022	<i>CASR, CFTR, CPA1, PRSS1, SPINK1, CTRC</i>
PGLNext (12 genes)	5504	<i>FH, MAX, MEN1, NF1, RET, SDHA, SDHAF2, SDHB, SDHC, SDHD, TMEM127, VHL</i>
ProstateNext^ (14 genes)	8845	<i>ATM, BRCA1, BRCA2, CHEK2, EPCAM, HOXB13, MLH1, MSH2, MSH6, NBN, PALB2, PMS2, RAD51D, TP53</i>
RenalNext (19 genes)	5900	<i>BAP1, EPCAM, FH, FLCN, MET, MITF, MLH1, MSH2, MSH6, PMS2, PTEN, SDHA, SDHB, SDHC, SDHD, TP53, TSC1, TSC2, VHL</i>

* AmbryScore for Breast is available as an add on to this panel if all of the following eligibility criteria are met:

- Female biological sex
- 18-84 years old
- Non-Ashkenazi Jewish, N. European ancestry
- No personal history of cancer (excluding non-melanoma skin cancer)
- No personal history of atypical hyperplasia or lobular carcinoma in situ (LCIS)
- No personal or family history of a mutation in a breast cancer susceptibility gene¹

¹ *ATM, BARD1, BLM* (if tested), *BRCA1, BRCA2, BRIP1, CDH1, CHEK2, FANCC* (if tested), *MRE11A, NBN, NF1, PALB2, PTEN, RAD50, RAD51C, RAD51D, STK11, TP53*

Note: AmbryScore supplemental ordering form is required for processing

^ AmbryScore for Prostate is available as an add on to this panel if all of the following eligibility criteria are met:

- Male biological sex
- 18-84 years old
- N. European ancestry
- No personal or family history of a mutation in a prostate cancer susceptibility gene²

² *ATM, BRCA1, BRCA2, CHEK2, EPCAM, HOXB13, MLH1, MSH2, MSH6, NBN, PALB2, PMS2, RAD51D, TP53*

Note: No additional supplemental ordering forms are required for processing