LLUMC Test Requisition for Tissue Culturing (Oncology)

COMPLETE ENTIRE FORM TO AVOID DELAYS

Ambry Genetics®
A Konica Minolta Company

Loma Linda University Medical Center Clinical Lab/Genetics
11223 Campus St. South Dock A Loma Linda, CA 92354 USA | CLIA# 05D0573839

PATIENT INFORMATION

Last Name	First Name	Middle Initial	DOB (MM/DD/YY)

Street Address	City	State	Zip

Preferred Contact Phone Number

Biological Gender: ☐ F ☐ M
Gender Identity (if different from marked): _____

Ethnicity: ☐ African American ☐ Asian ☐ Caucasian ☐ Hispanic ☐ Jewish (Ashkenazi) ☐ Portuguese ☐ Other: _____

Preferred Billing **Copy of front/back of insurance card required. Please complete Patient Assistance program information below, if applicable.* ☐ Insurance* ☐ Cash ☐ 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
☐ Do not start testing until I approve payment terms regarding estimated out-of-pocket costs

SPECIMEN TRANSPORT ☑ Room Temperature

Collection Date (MM/DD/YY): _____ Time: _____ ☐ AM ☐ 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 Ambry Genetics for testing. Sample will not be frozen for long-term storage.

Prenatal Specimen Details: Sample Type: ☐ Amniotic Fluid ☐ Direct Chorionic Villi ☐ Fetal Tissue Sample Amount: _____ Gestational Age at Collection: _____

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	

TEST ORDER

STEP 1: Select the indication for testing:

☐ Hereditary breast and ovarian cancer[1] ☐ Lynch[2] ☐ Hereditary polyposis[3]

☐ None ☐ Other: _____

1. *BRCA1/2* 2. *MLH1, MSH2, MSH6, PMS2, EPCAM* 3. *APC/MUTYH*

STEP 2: Select desired test:

☐ BRCAplus 8836 ☐ BreastNext 8820 ☐ CancerNext 8824 ☐ CancerNext-*Expanded* 8874
☐ ColoNext 8822 ☐ OvaNext 8830 ☐ ProstateNext 8845 ☐ CustomNext-*Cancer* 9510
☐ Other: _____

Optional: Add AmbryScore ☐ Breast (Additional Supplemental Ordering Form REQUIRED) ☐ Prostate

Will patient management be changed depending on the test results? ☐ Yes ☐ No STAT TEST: ☐ Date results needed (if known): _____

Order Code: 7030 - Tissue Culture (LLUMC/Clinical Lab/Genetics) ☐ Grow and Send ☐ 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 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 financially responsible for any amounts not covered by my insurer and responsible for sending Ambry money received from my health insurance company.

Ambry'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 Ambry 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 Ambry 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 ☐). Furthermore, all information on this TRF is true to the best of my knowledge. My signature applies to the attached letter of medical necessity.

**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 ambrygen.com/specimen-requirements for details.*

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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) 558-4832 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.

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Aliso Viejo, CA 92656 USA | Toll Free: 866.262.7943 | Fax: 949.900.5501 | ambrygen.com

Patient Name: _____ DOB: _____

Supplemental Information

Hereditary Cancer Multi-Gene Tests

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

* 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 gene[1]

[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 gene[2]

[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