Tumor Test Requisition Form - Page 1 of 3

COMPLETE ENTIRE FORM TO AVOID DELAYS

Ambry Genetics
A Konica Minolta Company
Aliso Viejo, CA 92656 USA
Toll Free: 866.262.7943 | Fax: 949.900.5501 | ambrygen.com

PATIENT INFORMATION

Name (Last, First, MI)	Date of Birth (MM/DD/YY)	Date of Death (If applicable)	Phone Number/Email

Address City State Zip	Biological Sex ☐F ☐M	Ethnicity: ☐African American ☐Asian ☐Caucasian ☐Hispanic ☐Jewish (Ashkenazi) ☐Portuguese ☐Other:

SPECIMEN INFORMATION

(Both normal sample (e.g. blood or saliva) and tumor tissue required. Please see specimen preparation instruction sheet for detailed specimen requirements.)

Blood/saliva*

Collection Date:

Specimen ID #:

*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

Tissue: ☐FFPE Block ☐Unstained slides (9) Specimen ID #:_____

Collection Date/Date Pulled From Archive: _____Collection Time:_____ AM/PM Archived specimen? ☐Yes ☐No

Fixative/preservative:_____ Body Site:_____ ☐Primary ☐Metastasis

Primary (if metastasis): _____ Permission to exhaust FFPE block? ☐ Yes ☐ No

Phlebotomy Services Request: ☐Phlebotomy draw ☐Insurance preverification first ☐Send kit to patient^

^As the patient's clinician, I am unaware of any potential for complication or difficulty in drawing blood for the listed patient(s). I understand that the phlebotomist has full authority to refuse to draw any patient if the safety of the phlebotomist and/or patient(s) are in question.

PATHOLOGY INFORMATION (REQUIRED)

☐ Please retrieve specimen (To facilitate this process, please complete the specimen forwarding form)

Pathology report for relevant tumor tissue specimen is REQUIRED for processing. Please include a copy when order is submitted. Tumor specimen will be returned unless otherwise indicated.

Institution Name	Pathologist	Phone	Fax

Address	City	State	Zip

ORDERING LICENSED PROVIDER/SENDING FACILITY

Facility Name (Facility Code)	Address	City	State /Country	Zip	Phone

Ordering Licensed Provider Name (Last, First)(Code)	NPI#	Phone	Fax/Email

ADDITIONAL RESULTS RECIPIENTS

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

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

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.

Signature Required for Processing Medical Professional Signature: Date:

☐ INSURANCE BILLING (Include copy of both sides of insurance card)

Patient Relation to Policy Holder? ☐Self ☐Spouse ☐Child	Name and DOB of Policy Holder (if not self)	
Insurance Company	Policy #	HMO Auth #

Out Of Pocket:

Ambry Genetics will start testing immediately. We will attempt to contact the patient if:

☐ Out-of-pocket amount is greater than $100 (default) ☐ There is any out-of-pocket amount

☐ Do not initiate testing until patient is contacted and approves payment terms regarding out-of-pocket

Patient agrees to contact regarding out-of-pocket amount by:

☐ Email ☐ Phone (includes texts) - confirm mobile # _____

☐ INSTITUTIONAL BILLING

Facility Name ☐ *Send invoice to facility address above*

Address

Contact Name

Phone Number | E-mail/Fax

☐ PATIENT PAYMENT

☐ Check (Payable to Ambry Genetics)

☐ Credit Card (Call 949-900-5795)

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.

For patient payment by credit card: I hereby authorize Ambry Genetics Corporation to bill my credit card as indicated above. In order to expedite consideration for eligibility for **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.

FOR NY RESIDENTS:

☐ I am a New York resident and I give Ambry Genetics permission to store my sample for longer than 60 days. **NOTE:** If left blank, consent is interpreted as "NO".

Signature Required For Insurance/Self-Pay Patients and NY Sample Storage Consent: Date:

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Patient Name: _____ DOB: _____

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INSURANCE ORDERING CHECKLIST

- ☐ Clinic notes (with pedigree if available)
- ☐ ICD-10 code(s)
- ☐ Clinician & patient signatures
- ☐ Insurer-specific forms (i.e. ABN), if applicable
- ☐ Front/back copy of insurance card(s)

PATIENT CLINICAL HISTORY (Please indicate if diagnosis is active)

☐ No personal history of cancer ☐ History of allogenic bone marrow or peripheral stem cell transplant* ICD-10 code(s):

Cancer/Tumor	Active	Age at Dx	Pathology and Other Info
Breast	☐		Type: ER ☐(+) ☐(-) ☐unk PR ☐(+) ☐(-) ☐unk HER2/neu ☐(+) ☐(-) ☐unk
Colorectal	☐		Location:
Uterine	☐		
Ovarian	☐		☐ Fallopian tube ☐ Primary peritoneal
Prostate	☐		Gleason Score: Metastatic: ☐Y ☐N
Other Cancer	☐		Type:

Other clinical history:

**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 for details.*

PATIENT GENETIC TESTING HISTORY

Lynch syndrome tests only:
This section must be completed for Medicare beneficiaries

☐ No previous molecular and/or genetic testing

Genetic testing Test(s) performed:_____

Result(s):_____

Please include copies of any previous genetic test results.

Microsatellite instability analysis:
☐ Stable (MSS) ☐ Unstable/high (MSI-H) ☐ Unstable/low (MSI-L)

IHC, if multiple primaries, tumor used:_____
☐ Proteins present: _____ ☐ Proteins absent: _____

☐ Tissue is unavailable or insufficient for IHC/MSI testing

FAMILY HISTORY*

**Completing this section is not mandatory for ordering if a pedigree and/or clinical note with family history is supplied, but is recommended and helps with results interpretation and claims filing.*

☐ None (maternal) ☐ None (paternal) ☐ Maternal history unknown ☐ Paternal history unknown

Relation to patient	Maternal	Paternal	Cancer/Polyp Type	Dx age	Relation to patient	Maternal	Paternal	Cancer/Polyp Type	Dx age
	☐	☐				☐	☐		
	☐	☐				☐	☐		
	☐	☐				☐	☐		

TESTS REQUESTED

Check to order	Test Name	Test Code	Description
Both normal sample (e.g. blood or saliva) and tumor tissue are required. Please see specimen preparation instruction sheet for more detailed specimen requirements.			
☐	Lynch syndrome paired testing*	8982	Paired tumor and germline testing of *MLH1, MSH2, MSH6, PMS2, + EPCAM* del/dup
☐	TumorNext- *Lynch* *	8980	Paired tumor and germline testing of *MLH1, MSH2, MSH6, PMS2,* and *EPCAM*; microsatellite instability (MSI) and *MLH1* promoter hypermethylation analysis
☐	TumorNext-*Lynch* plus ColoNext*	8981	TumorNext-*Lynch* (described above) plus germline analysis of 12 additional genes
☐	TumorNext-*Lynch* plus OvaNext*	8983	TumorNext-*Lynch* (described above) plus germline analysis of 20 additional genes
☐	TumorNext-*Lynch* plus CancerNext*	8984	TumorNext-*Lynch* (described above) plus germline analysis of 29 additional genes
☐	Add on *BRAF* (V600E), *KRAS*, and *NRAS* targeted analysis (*This can only be applied to test options above.*)		
☐	Microsatellite instability (MSI) analysis*	8702	
☐	*MLH1* promoter hypermethylation analysis*	7978	
**Colon (excluding polyps without high grade dysplasia) and endometrial tumors will be accepted. For other cancer types, please discuss with your Ambry Account Manager.*			
☐	TumorNext-*BRCA***	9810	Paired tumor and germline analysis of *BRCA1* and *BRCA2*
☐	TumorNext-*HRD***	9811	Paired tumor and germline analysis of *BRCA1* and *BRCA2* plus 9 additional genes; methylation analysis of *BRCA1* and *RAD51C*
☐	TumorNext-*HRD* plus OvaNext**	9812	TumorNext-*HRD* (described above) plus germline analysis of 14 additional genes
☐	TumorNext-*HRD* plus CancerNext**	9813	TumorNext-*HRD* (described above) plus germline analysis of 23 additional genes
***Ovarian tumors (including Fallopian tube and primary peritoneal) will be accepted. For other cancer types, please discuss with your Ambry Account Manager.*			

For assistance regarding requested tumor samples, please contact tumorsampleinquiry@ambrygen.com or call 949.900.5783.

Notes:

For complete gene lists or additional test information, please visit ambrygen.com

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Tumor Specimen Forward Request - Page 3 of 3

Form is not required for processing, however, to streamline obtaining your patient's tumor specimen from Pathology, please submit this form with a copy of the completed Tumor Test Requisition Form (TRF). Otherwise, additional paperwork may be required to obtain tumor. If you would like to facilitate the submission of your patient's tumor from Pathology to Ambry, please submit this form with a copy of the TRF directly to relevant Pathology department.

I, _____ am requesting that the tissue sample for
(ordering medical professional name)

_____ ,DOB: _____ be sent to Ambry Genetics for _____ testing.
(patient name)

_____ Date: _____
(ordering medical professional signature)

Pathology Information

Institution Name _____

Address _____ Phone _____

☐ Once testing is complete, return specimen to Pathology at address above

☐ Once testing is complete, return specimen to other location, please specify:

Institution Name _____

Address _____ Phone _____

Specimens can be submitted as either:

1. Formalin fixed paraffin embedded (FFPE) tumor tissue block (preferred) or
2. Nine (9) unstained slides mounted with FFPE tissue sections cut at 10 micron thickness, unbaked and one (1) unstained slide with FFPE tissue sections cut at 5 micron thickness, unbaked

NOTE:
- Tumor block from resection/excision specimen is preferred. Please note that small size tissue samples with tumor area <25 mm^2 (core biopsy specimens, colonoscopic or other endoscopic biopsy specimens), hypocellular, fibrotic, fatty, necrotic samples or samples with lower tumor cell content (<20% viable tumor cellularity) may not yield enough DNA for analysis and may require additional unstained slides. Moreover, submission of these sample types may result in requests for permission to exhaust the block or an alternate tumor tissue block to obtain sufficient DNA for testing. When choosing a block for submission, please select one with the largest tumor focus or highest tumor cellularity.
- Nucleated cells cellularity: at least 80%
- Tumor content /neoplastic cellularity: Viable tumor cell nuclei should constitute at least 20% of total number of all nucleated cells.

<u>Acceptable Tumor types:</u>
- TumorNext-*Lynch*: Currently only colorectal cancers and endometrial cancers are accepted. A tumor block on which previously run DNA mismatch repair protein immunohistochemistry studies is preferred for TumorNext-*Lynch* testing.
- TumorNext-*BRCA* and *HRD*: Currently only ovarian cancers (including Fallopian tube and primary peritoneal) are accepted
- For other cancer types, please discuss with your Ambry Account Manager

<u>Unacceptable specimens:</u>
- Less than 20% viable tumor cellularity
- Specimens fixed/processed in alternative fixatives other than 10% neutral buffered formalin (*e.g.* Bouins, Zenker's, B5, or heavy metal fixatives)
- Decalcified specimens

Please include a copy of Pathology report, this form, and the Ambry Tumor TRF along with the specimen. Specimens received must have at least two patient identifiers in order to avoid discrepancies. During hot weather, it is advisable to include a cooling pack with the specimen when shipping to avoid heat damage.

For additional details regarding specimen preparation or shipping, please see the attached Specimen Preparation and Shipment Instructions.

Specimens may be shipped in an Ambry specimen submission kit. These are available to order at ambrygen.com/order-sample-kit at no cost.

<u>Please ship the specimen overnight to</u>: Accessioning at Ambry Genetics, 7 Argonaut, Aliso Viejo, CA 92656 USA