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

COMPLETE ENTIRE FORM TO AVOID DELAYS

PATIENT INFORMATION

Name (Last, First, MI)

DOB (MM/DD/YY) | Biological Sex ☐F ☐M | Phone Number/Email

Address | City | State | Zip

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

FAMILY HISTORY

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

Relation to patient	Mat.	Pat.	Diagnosis	Dx age
	☐	☐		
	☐	☐		
	☐	☐		
	☐	☐		
	☐	☐		

PATIENT HISTORY (Supply clinic notes and pedigree when possible)

PERSONAL HISTORY OF CANCER: ☐No personal history of cancer

Type(s): MSI result:

Age(s) at Dx: IHC result:

Polyp history: Type(s) # of polyps: Location:

Other clinical history:

SPECIMEN INFORMATION*

Type(s) ☐Blood (EDTA preferred) ☐Saliva ☐DNA ☐Other:

☐ Personal history of allogenic bone marrow or peripheral stem cell transplant

Collection Date | Specimen ID | MRN

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.

*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.

ORDERING PHYSICIAN/SENDING FACILITY (Each listed person will receive a copy of the report)

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

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

Genetic Counselor Name (Last, First) (Code) | Phone/Fax/Email | Medical Professional 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:

INDICATIONS FOR TESTING (Check all that apply)

☐Diagnostic ☐Family history ☐Positive or normal control ☐Other ICD-10 code(s):

TEST REQUESTED - GI CANCER TEST OPTIONS

If this TRF is sent to Ambry without or ahead of the sample, it will be treated as a preverification. If test ordered is different than the test preverified, we will honor what is on the TRF order form with the sample.

For multiple tests, testing will be run concurrently (initiated at the same time) unless otherwise specified. For reflexive testing (second test starts pending first test outcome), indicate the order of reflexive tests in the notes section or next to the test check box. For reflex test orders, any positive findings (pathogenic/likely pathogenic) in the first test will be reported, and the second test will be cancelled; all other findings will automatically reflex (including VUS).

Multi-Gene Orders: For multi-gene orders, first select which of the following conditions is clinically indicated based on the patient's personal and/or family history:

☐Adenomatous polyposis (*APC/MUTYH*)
☐Hereditary breast and ovarian cancer (*BRCA1/2*)
☐Lynch syndrome/HNPCC (*MLH1, MSH2, MSH6, PMS2, EPCAM*)
☐Testing is clinically indicated for other gene(s):
☐None of the above

To complete your multi-gene order, please select a test option below (see supplemental pages for details):

☐ColoNext (8822) ☐PancNext (8042) ☐Pancreatitis panel (8022)
☐CancerNext-*Expanded* (8874) ☐CancerNext (8824)
☐Other Test Code: _____ Test Name: _____

Single Syndrome Orders

Single gene analysis is available for listed panels. Visit ambrygen.com/hereditary-cancer-single-gene-tests for details.

☐Lynch syndrome (8517)^
Test Code(s): Gene/Test Name(s):
^*If patient has Medicare and only Lynch is being ordered, please order 8515.*

Single Site Analysis (SSA) (Include relative report)

Gene(s): _____ Mutation(s): _____
Previously Tested Relative (name): _____
Relationship to Relative: _____
Positive control sample: ☐ will be provided ☐ already at Ambry ☐ not available

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

☐ 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 # _____

☐ GRATIS (Check for pre-approved gratis testing)

☐ 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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REQUIRED INSURANCE ORDERING CHECKLIST

- ☐ Clinic Notes (Pedigree if available)
- ☐ ICD-10 Code(s)
- ☐ Clinician & Patient Signatures
- ☐ Insurer Specific Forms (i.e. ABN)
- ☐ Copy of Insurance Cards

Cancer Test - Supplemental Information - Page 2 of 2

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 68 genes) Required: complete CustomNext-*Cancer* supplemental form. ambrygen.com/forms	9510	*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, NTHL1, 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*
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 (4 genes)	**8022**	***CFTR, 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*

Updated Ordering Process (as of June 8, 2016)

We have improved the ordering and reporting process for our hereditary cancer panels. This helps confirm that testing for one or more of the following genes is clinically indicated: *APC*, *BRCA1, BRCA2, EPCAM, MLH1, MSH2, MSH6, MUTYH,* and *PMS2*.

If you are ordering a multi-gene test, please first select a clinically indicated condition and complete your order by selecting a multi-gene order.

Please indicate if your patient meets clinical and/or insurance testing criteria,or if the testing is otherwise clinically indicated for one or more of the following conditions:

- Adenomatous polyposis (*APC/MUTYH*)
- Hereditary breast and ovarian cancer (*BRCA1/2*)
- Lynch syndrome/HNPCC (*MLH1, MSH2, MSH6, PMS2, EPCAM*)

If testing is not clinically indicated for your patient for any of the listed options, please either fill in the other gene(s) option or select "none of the above".

To complete your multi-gene order, please select one of the appropriate test options and/or select "other" and enter an appropriate test code(s)/test name(s).

For single gene orders, please enter the gene(s) and/or test name(s), as well as the relevant test code in the single gene orders section.

For additional details about our single gene testing options, please visit ambrygen.com/hereditary-cancer-single-gene-tests.

Example

For a ColoNext multi-gene order, when Lynch syndrome testing is clinically indicated for the patient:

Multi-Gene Orders: For multi-gene orders, first select which of the following conditions is clinically indicated based on the patient's personal and/or family history:

- ☐ Adenomatous polyposis (*APC/MUTYH*)
- ☐ Hereditary breast and ovarian cancer (*BRCA1/2*)
- ☑ Lynch syndrome/HNPCC (*MLH1, MSH2, MSH6, PMS2, EPCAM*)
- ☐ Testing is clinically indicated for other gene(s):
- ☐ None of the above

To complete your multi-gene order, please select a test option below (see supplemental pages for details):

☑ ColoNext (8822) ☐ PancNext (8042) ☐ Pancreatitis panel (8022)
☐ CancerNext-*Expanded* (8874) ☐ CancerNext (8824)
☐ Other Test Code: _____ Test Name: _____

EXAMPLE

For single gene genetic testing of *CDH1*:

Single Syndrome Orders

Single gene analysis is available for listed panels. Visit ambrygen.com/hereditary-cancer-single-gene-tests for details.

☐ Lynch syndrome (8517)^

Test Code(s): 4726 Gene/Test Name(s): CDH1

^ *If patient has Medicare and only Lynch is being ordered, please order 8515.*

EXAMPLE

Single Site Analysis (SSA) (Include relative report)

Gene(s): _____ Mutation(s): _____

Previously Tested Relative (name): _____

Relationship to Relative: _____

Positive control sample: ☐ will be provided ☐ already at Ambry ☐ not available