Ambry Genetics® | LifeStrands

# Supporting Cancer Patients with Germline Testing

## CancerNext® | Multi-Gene Hereditary Cancer Testing

Adding germline testing for patients pursuing somatic testing provides an additional layer of information that can help complete the clinical interpretation of a patient's cancer. More importantly, hereditary cancer results help identify patients who may benefit from mutation-guided medical management.

### Support Determination of Cancer Origin
Identifying hereditary causes to cancer may help guide risk-reducing measures.

### Inform Treatment Options
Patients with certain hereditary dispositions may qualify for PARP inhibitors[1] or certain immunotherapies.[2]

### Advise Implications of Radiation Treatment[3]
Patients harboring certain hereditary dispositions may be at an increased risk for cancer secondary to radiation therapy.

### Identify At-Risk Family Members
Identifying hereditary causes to cancer may help guide risk-reducing measures.

## Genetic Testing is Underutilized in Cancer Patients[4]

**5–10%**[5] of cancer patients have a germline variant

**~1 in 3**[6] cancer patients with a germline variant could benefit from PARP inhibitors[1]

# How Ambry Can Support Your Practice with Germline Testing

## CancerNext®

### Multi-Gene Hereditary Cancer Testing

CancerNext (36 gene) and CancerNext-*Expanded*® (77 gene) multi-gene panels provide genetic cancer insight by identifying disease-causing variants. Designed to maximize diagnostic yield for patients with a personal history of cancer, the gene coverage overlaps with several organ specific cancers including, colorectal, breast, ovarian, prostate and pancreatic.

## Post-Test Genetic Counseling

Access to our team of genetic counselors gives oncologists the flexibility to focus on treatment and medical management, where applicable.

## Family Variant Testing

Testing for all blood relatives is available within 90 days of the original report if the proband was tested at Ambry. Family testing is done via specific site analysis for pathogenic or likely pathogenic variants. (Excludes SNP array and applies to single gene, panel or exome testing.)

## Genetic Testing is Underutilized in Cancer Patients.[4]

## We Want to Change That.


**References**

1. "PARP Inhibitors." Cancer Treatment Centers of America, 23 Dec. 2021, www.cancercenter.com/treatment-options/parp-inhibitors.
2. https://doi.org/10.1186/s40164-021-00231-4
3. https://doi.org/10.1093/jrr/rrab009
4. DOI: 10.1200/JCO.18.01854 *Journal of Clinical Oncology 37,* no. 15 (May 20, 2019) 1305-1315.
5. Anon, Family Cancer Syndromes. American Cancer Society. Available at: https://www.cancer.org/cancer/cancer-causes/genetics/family-cancer-syndromes.html [Accessed May 9, 2022]
6. Data on File


CancerNext and CancerNext-Expanded are laboratory developed tests with performance characteristics determined by the CLIA-certified laboratory performing the test. These tests have not been cleared or approved by the US Food and Drug Administration (FDA).


CONTACT INFORMATION

**LifeStrands Genomics**

61 Science Park Road The Galen #03-13/14 SG 117525 | T: (65) 6422 6322 | E: enquiry@lifestrandsgx.com | W: www.lifestrandsgx.com





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# Germline Testing for Hereditary Cancer

## Reference Guide

## Guidelines Recommend Genetic Testing For Hereditary Cancer

**The American Society of Clinical Oncology (ASCO)** recommends that genetic testing be offered to individuals with suspected inherited (genetic) cancer risk in situations where test results can be interpreted, and when they affect medical management of the patient. It is sufficient for cancer risk assessment to evaluate genes of established clinical utility that are suggested by the patient's personal and/or family history.

*Adapted from J Clin Oncology, 2015*

## Patients with a Personal and/or Family History Suggestive of Hereditary Cancer May Benefit From CancerNext-*Expanded*

If your patient has a personal or family history of **ANY** of the following signs* of hereditary cancer, genetic testing should be considered:

| CANCER TYPE | MULTIPLE CANCERS OR OTHER CLINICAL RISK FACTORS | EARLY-ONSET CANCERS | ANCESTRY |
|---|---|---|---|
| MALE BREAST<br>OVARIAN<br>PANCREATIC<br>METASTATIC PROSTATE CANCER | 2 OR MORE primary cancers in the same person<br>3 OR MORE cancers on the same side of the family<br>10 OR MORE colorectal polyps in a person's lifetime | ANY OF THE FOLLOWING CANCERS DIAGNOSED BEFORE 46 YEARS of AGE:<br>Breast, colorectal, uterine | ASHKENAZI JEWISH WITH BREAST CANCER |

** This is a suggested list adapted from published genetic testing guidelines*

# CancerNext-*Expanded* Genes and Associated Cancers

Turnaround time: 14-21 days

77 gene hereditary cancer test

Management guidelines available for many included genes

| GENE(S) | ASSOCIATED CANCERS | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Breast | Ovarian | Colorectal | Uterine | Pancreatic | Prostate | Gastric | Kidney | Endocrine** | Central Nervous System | Melanoma | Other |
| *AIP* | | | | | | | | | | ✓ | | |
| *ALK* | | | | | | | | | | ✓ | | ✓ |
| *APC** | | | ✓ | | ✓ | | ✓ | | ✓ | ✓ | | ✓ |
| *ATM** | ✓ | | | | ✓ | ✓ | | | | | | |
| *AXIN2** | | | ✓ | | | | | | | | | |
| *BAP1* | | | | | | | | ✓ | | | ✓ | ✓ |
| *BARD1* | ✓ | | | | | | | | | | | |
| *BLM* | ✓ | | ✓ | | | | | | | | | |
| *BRCA1** | ✓ | ✓ | | | ✓ | ✓ | | | | | | |
| *BRCA2** | ✓ | ✓ | | | ✓ | ✓ | | | | | ✓ | |
| *BMPR1A, SMAD4** | | | ✓ | | | | ✓ | | | | | |
| *BRIP1** | ✓ | ✓ | | | | | | | | | | |
| *CDC73* | | | | | | | | ✓ | | | | ✓ |
| *CDH1** | ✓ | | | | | | ✓ | | ✓ | | | |
| *CDK4* | | | | | | | | | | | ✓ | |
| *CDKN1B* | | | | | | | | | ✓ | ✓ | | ✓ |
| *CDKN2A* | | | | | ✓ | | | | | ✓ | ✓ | |
| *CHEK2** | ✓ | | ✓ | | | ✓ | | | | | | ✓ |
| *CTNNA1* | | | | | | | ✓ | | | | | |
| *DICER1* | | ✓ | | | | | | | | ✓ | | ✓ |
| *EGFR* | | | | | | | | | | | | ✓ |
| *EPCAM* | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | ✓ | | ✓ |
| *EGLN1* | | | | | | | | | ✓ | | | |
| *FANCC* | ✓ | | | | | | | | | | | |
| *FH* | | | | | | | | ✓ | ✓ | | | ✓ |
| *FLCN* | | | | | | | | ✓ | | | | |
| *GALNT12* | | | ✓ | | | | | | | | | |
| *GREM1** | | | ✓ | | | | | | | | | |
| *HOXB13* | | | | | | ✓ | | | | | | |
| *KIF1B* | | | | | | | | | ✓ | | | |
| *KIT* | | | | | | | | | | | | ✓ |
| *LZTR1* | | | | | | | | | | ✓ | | |
| *MAX* | | | | | | | | | ✓ | | | |
| *MEN1* | | | | | | | | | ✓ | ✓ | | ✓ |
| *MET* | | | | | | | | ✓ | | | | |
| *MITF* | | | | | | | | ✓ | | | ✓ | |

# CancerNext-*Expanded* Genes and Associated Cancers

| GENE(S) | ASSOCIATED CANCERS | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Breast | Ovarian | Colorectal | Uterine | Pancreatic | Prostate | Gastric | Kidney | Endocrine** | Central Nervous System | Melanoma | Other |
| *MLH1*, MSH2*, MSH6*, PMS2** | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | ✓ | | ✓ |
| *MSH3** | | | ✓ | | | | | | | | | |
| *MUTYH** | ✓ | | ✓ | | | | | | | | | |
| *NBN** | | | | | | | | | | | | ✓ |
| *NF1** | ✓ | | | | | | | | ✓ | ✓ | | ✓ |
| *NF2* | | | | | | | | | ✓ | ✓ | | ✓ |
| *NTHL1** | | | ✓ | | | | | | | | | |
| *PALB2** | ✓ | ✓ | | | ✓ | ✓ | | | | | | |
| *PDGFRA* | | | | | | | | | | | | ✓ |
| *PHOX2B* | | | | | | | | | | ✓ | | ✓ |
| *POLD1, POLE** | | | ✓ | | | | | | | | | |
| *POT1* | | | | | | | | | | ✓ | ✓ | |
| *PRKAR1A* | | | | | | | | | ✓ | ✓ | | ✓ |
| *PTCH1* | | | | | | | | | | ✓ | | ✓ |
| *PTEN** | ✓ | | ✓ | ✓ | | | | ✓ | ✓ | ✓ | ✓ | ✓ |
| *RAD51C** | ✓ | ✓ | | | | | | | | | | |
| *RAD51D** | ✓ | ✓ | | | | ✓ | | | | | | |
| *RB1* | | | | | | | | | | | ✓ | ✓ |
| *RECQL* | ✓ | | | | | | | | | | | |
| *RET* | | | | | | | | | ✓ | | | |
| *SDHA, SDHAF2, SDHB, SDHC, SDHD* | | | | | | | | ✓ | ✓ | | | |
| *SMARCA4* | | ✓ | | | | | | | | ✓ | | ✓ |
| *SMARCB1* | | | | | | | | ✓ | | ✓ | | ✓ |
| *SMARCE1* | | | | | | | | | | ✓ | | |
| *STK11** | ✓ | ✓ | ✓ | | ✓ | | | | | | | ✓ |
| *SUFU* | | | | | | | | | | ✓ | | ✓ |
| *TMEM127* | | | | | | | | | ✓ | | | |
| *TP53** | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| *TSC1, TSC2* | | | | | | | | ✓ | | ✓ | | ✓ |
| *VHL* | | | | | | | | ✓ | ✓ | ✓ | | ✓ |
| *XRCC2* | ✓ | | | | | | | | | | | |

*Management guidelines available

**Endocrine indicates at least one of the following: paraganglioma, pheochromocytoma, thyroid cancer, parathyroid cancer, carcinoid tumors, pancreatic neuroendocrine tumors, and/or adrenal tumors

## Results of Genetic Testing May Inform Personalized Medical Management

The potential benefits of genetic testing for hereditary cancer include:

Inform treatment recommendations[1-9]

Consideration of risk-reducing measures, as appropriate

Determine eligibility for clinical trials

Identify at-risk family members to inform cancer risks and medical management

## Supporting Access to Patient Testing

### Testing for Family Members

Testing for all blood relatives is available within 90 days of the original report if the patient was tested at Ambry Genetics. Family testing is done via specific site analysis for pathogenic or likely pathogenic variants. (Excludes SNP array and applies to single gene, panel, or exome testing).

## About Ambry Genetics®

Ambry Genetics, a subsidiary of REALM IDx, Inc., excels at translating scientific research into clinically actionable test results based on a deep understanding of the human genome and the biology behind genetic disease. Ambry has an unparalleled track record of discoveries over 20 years and a database that continually expands through collaboration with academic, corporate and pharmaceutical partners. Being first to market with innovative products and comprehensive analysis, Ambry enables clinicians to confidently inform patient health decisions. For more information, please visit ambrygen.com.


References

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7. Mirza, *et al.* N Engl J Med. 2016;375:2154-2164
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