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CARIS® LIFE SCIENCES

CancerNext-*Expanded*®
Available with +RNAinsight®

REFERENCE GUIDE

Multiple 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

The Society of Gynecologic Oncology (SGO) recommends that all women diagnosed with epithelial ovarian, Fallopian tube, and peritoneal cancers should receive genetic counseling and consider genetic testing, even in the absence of a family history of cancer.

Adapted from SGO Clinical Practice Statement, October 2014

If your patient has a personal or family history of any of the following signs^ of hereditary cancer, guidelines recommend genetic testing:

CANCER TYPE	MULTIPLE CANCERS OR OTHER CLINICAL RISK FACTORS	EARLY-ONSET CANCERS	ANCESTRY
MALE BREAST OVARIAN PANCREATIC METASTATIC PROSTATE CANCER	2 OR MORE primary cancers in the same person 3 OR MORE cancers on the same side of the family 10 OR MORE colorectal polyps in a person's lifetime	ANY OF THE FOLLOWING CANCERS DIAGNOSED BEFORE 50 YEARS OF AGE: Breast, colorectal, uterine	ASHKENAZI JEWISH WITH BREAST CANCER

^Adapted from published genetic testing guidelines

CancerNext-*Expanded* Genes and Associated Cancers

Turnaround time: 14-21 days

77 gene hereditary cancer test

NCCN® 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	✓											

Genes eligible for +RNAinsight®. For more information, visit rnainsight.com

*NCCN 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

+RNAinsight Provides an Additional Line of Evidence To:

- Find More Mutations[10]
- Decrease Variants of Unknown Significance[11]
- Provide More Accurate Results to Inform Patient Care[10,11]

Results of Genetic Testing May Inform Personalized Medical Management

The potential benefits of germline genetic testing 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

Technical Specifications

Sample Requirements Use ONLY the tubes in the Caris Blood Shipper Kit	Sensitivity	Specificity	Average Depth of Coverage (DNA)
For DNA-Only Collection: Two 10 mL PAXgene, blue top tubes of blood **To add +RNAinsight:** Add one PAXgene red top RNA tube	>99%	>99%	500x to 1,000x

Ambry Genetics - Elevating the Standard of Care™

No-Cost Testing for Family Members

We offer family variant testing at no additional cost for all blood relatives of patients who are found to have a pathogenic or likely pathogenic variant. No-cost testing of blood relatives must be completed within 90 days of the original Ambry/Caris combined report date.

Accessible and Affordable Genetic Testing

We are contracted with the majority of U.S. health insurance companies. 4 out of 5 patients pay $0 out of pocket, and for those who pay, the average amount is less than $100. No additional cost for +RNAinsight.

References 1. Banerjee S & Kaye S. Curr Oncol Rep. 2011 Dec;13(6):442-9 2. Burgess M & Puhalla S. Front Oncol. 2014 Feb 27;4:19 3. Yamamoto KN et al. PLoS One. 2014 Aug 26;9(8): e105724 4. Moore et al. NEJM 2018 Oct 21 (Epub ahead of print) 5. Ledermann, et al. Lancet Oncol. 2014;15(8):852-861 6. Pujade-Lauraine, et al. Lancet Oncol. 2017;18:1274-1284 7. Mirza, et al. N Engl J Med. 2016;375:2154-2164 8. Coleman RL, et al. Lancet. 2017 Oct 28;390(10106):1949-1961 9. Swisher, et al. Lancet Oncology 2017;18: 75-87 10. Landrith T et al. npj Precis Oncol. 2020 Dec 24;4(1):1–9. 11. Karam R et al. JAMA Netw . 2019 Oct 2;2(10):e1913900.

One Enterprise, Aliso Viejo, CA 92656 USA Toll Free +1.866.262.7943 Fax +1.949.900.5501 ambrygen.com