

Example HRRm Commercial Laboratory Options*

					HRR Gene Mutation Coverage															
Commercial Laboratories	Example Tests*	Sample	Somatic HRRm?	Germline HRRm?	ATM	BRCA1	BRCA2	CDK12	CHEK2	PALB2	RAD51C	FANCL	BARD1	RAD51D	ATR	FANCA	MLH1	MRE11A	NBN	
Ambry	CancerNext Expanded**1	Blood/Saliva	No	Yes	●	●	●		●	●	●		●	●				●		
	ProstateNext**2	Blood/Saliva	No	Yes	●	●	●		●	●				●				●		●
BioReference	OnkoSight™ Advanced*3	Tissue	Yes	Incidental ^b	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
	OnkoRisk™ Plus**4,5	Blood/Saliva	No	Yes	●	●	●		●	●	●	●	●	●		●	●	●	●	●
Caris Life Sciences	MI Tumor Seek™**6	Tissue	Yes	No	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
	MI Profile™**7	Tissue	Yes	No	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
	Assure Liquid™**7	Blood	Yes	Incidental ^b	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Exact Sciences	Riskguard™**8,9	Blood/Saliva	No	Yes	●	●	●		●	●	●		●	●				●		
	OncoExTra*10	Tissue	Yes	No	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Foundation	FoundationOne® Liquid ¹¹	Blood	Yes	Incidental ^b	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
	FoundationOne® CDx ¹²	Tissue	Yes	Incidental ^b	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
GoPath	ProstateNOW**13,14	Blood/Saliva	No	Yes	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
	OncoTarget500**15	Tissue	Yes	Incidental ^b	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Guardant	Guardant360® CDx ¹⁶	Blood	Yes	Incidental ^b	●	●	●	●										●		
	Guardant360®**17	Blood	Yes	Incidental ^b	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Labcorp	Multi-Cancer (Invitae)* ¹⁸	Blood/Saliva	No	Yes	●	●	●		●	●	●		●	●				●		●
	OmniSeq Insight**19,20	Tissue	Yes	Incidental ^b	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
	VistaSeq Hereditary* ²¹	Blood/Saliva	No	Yes	●	●	●		●	●	●		●	●				●		●
Myriad	MyRisk®**22	Blood/Saliva	No	Yes	●	●	●		●	●	●		●	●				●		
	Precise™ Tumor**23	Tissue	Yes	Incidental ^b	●	●	●	●	●	●				●		●	●			
NeoGenomics	NeoTYPE® HRR Profile**24	Tissue	Yes	Incidental ^b	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Quest	Solid Tumor Expanded**25	Tissue	Yes	Incidental ^b	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
	Comp Hereditary Cancer**26	Blood/Saliva	No	Yes	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Tempus	Tempus xT Tissue**27	Tissue	Yes	Incidental ^b	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
	Tempus xF+ Liquid**28	Blood	Yes	Incidental ^b	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
	Tempus xG+ (germline)**29	Blood/Saliva	No	Yes	●	●	●		●	●	●		●	●				●		●

HRR, homologous recombination repair; HRRm, homologous recombination repair gene-mutated; NCCN, National Comprehensive Cancer Network.

^aOther tests may be available that could cover HRR genes. These are the tests that are most likely being used to test for prostate cancer.

^bRisk-conferring germline mutations in tumor tests are incidental findings and should be evaluated in a germline setting.³⁰

* Not FDA-approved tests. These are Laboratory Developed Tests (LDTs), which are in vitro diagnostic products (IVDs) that are intended for clinical use and are designed, manufactured, and used within a single clinical laboratory which meets certain laboratory requirements. Although LDTs must be certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and meet the regulatory requirements under CLIA to perform high complexity testing, these tests are not individually FDA-approved.

The diagnostic tests listed are generally commercially available HRR alteration gene panels. List is current as of October 2024. Tests listed may include analysis of genes outside of HRR pathways.

This information is intended as educational only and is not intended as a complete list of available testing options. While diagnostic testing may assist providers in identifying appropriate treatment for patients, the decision and action should be decided by a provider in consultation with the patient. Pfizer is not responsible for any test provider and does not endorse or recommend any particular diagnostic test. The accuracy and results of diagnostic tests vary, and Pfizer shall have no liability arising from such testing. The information provided herein should in no way be considered a guarantee of coverage, reimbursement, availability, or patient assistance. Providers should contact third-party laboratories for information.

- This table includes example commercially available tests for HRR mutations. Not all of these tests are FDA-approved tests. These tests vary in their coverage of HRR genes and may assess somatic and/or germline HRR gene mutations¹⁻²⁹
- NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) recommend a multigene panel that assesses a number of HRR gene mutations for somatic and for germline testing³¹
- This is not an exhaustive list of testing options. The decision to test and which test to use should be decided by the provider in consultation with the patient
- For more information on individual tests, providers should contact third-party laboratories
- It is important to note that risk-conferring germline mutations uncovered in tumor tests are incidental findings and should be evaluated in a germline setting³⁰

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- 31 Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) for Prostate Cancer V4.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed August 29, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.



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