oncoExTra®

Covered by MEDICARE

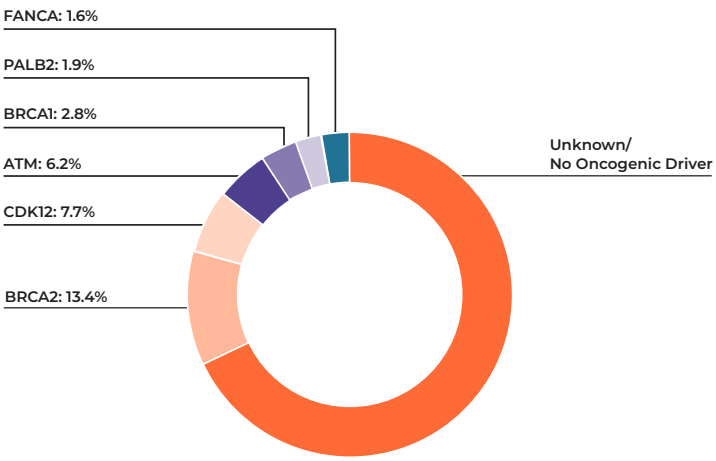
DNA is only half the genomic story

In advanced Prostate Cancer, ultra-comprehensive genomic profiling requires more than DNA alone.

- Prostate cancer is the **most** commonly diagnosed cancer amongst men in the United States.[1]
- Prostate cancer is the **2nd** leading cause of cancer death in the U.S., second only to lung cancer.[1]
- About **1 in 8** men will be diagnosed with prostate cancer during their lifetime.[1]

Scientific studies have shown that approximately 25% of mCRPC is associated with defects of the signaling pathway associated with the key repair mechanisms involved when DNA is damaged[2]

Up to 23.7% of metastatic castrate resistant Prostate Cancers have an actionable finding with comprehensive genomic profiling (CGP)[3]



Of **60,000** advanced prostate cancer patients that can be informed through CGP, approximately **14,000 patients** will have actionable actionable findings in 1 or more HRR genes[5]

The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer recommendations on Genomic Profiling:[4]

- Tumor testing for somatic homologous recombination gene mutations can be considered in patients with regional (N1) prostate cancer and is recommended for those with metastatic disease.
- Molecular testing of a tumor offers the potential of added insight into the “biologic behavior” of a cancer that could thereby aid in the clinical decision-making.
- Use to screen for clinical trial eligibility

The use of PARP inhibitors in patients with castration-resistant metastatic prostate cancer is associated with improved progression-free survival[6]

More variants, more actionability with **OncoExTra®**

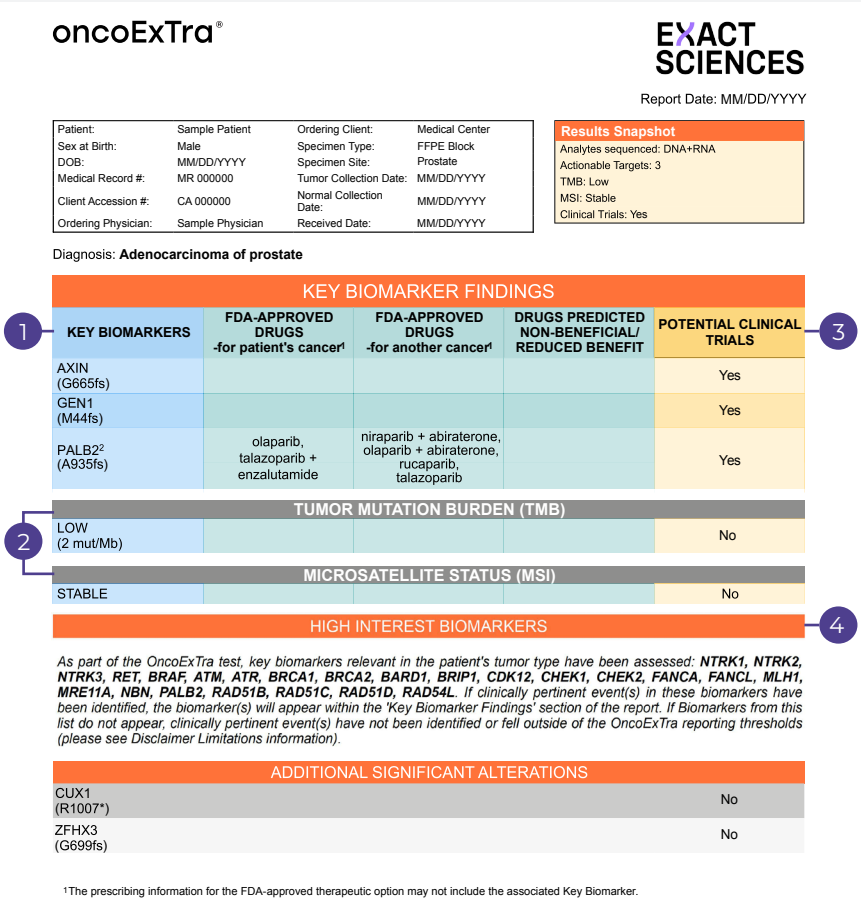
A DNA+RNA profiling test for solid tumors that offers:[7]

- Interrogation of nearly 20K genes
- 98.8% sensitivity / >99.9% specificity
- Patient-matched tumor-normal sequencing
- Optional immunohistochemical (IHC) panels/single stain for added detail†

41% of fusions detected at the RNA level alone[7,*]

In a retrospective analysis, 77% of prostate samples were found to harbor at least 1 actionable mutation[7]

† IHC testing is not currently available in New York State
*Retrospective analysis of 1,509 clinical reports, of which 1,261 included both DNA and RNA profiling. OncoExTra detected clinically actionable RNA fusions in 5.9% (75/1,261) of samples. 41% had RNA findings only (31/75)



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EXACT SCIENCES

Report Date: MM/DD/YYYY

Patient:	Sample Patient	Ordering Client:	Medical Center
Sex at Birth:	Male	Specimen Type:	FFPE Block
DOB:	MM/DD/YYYY	Specimen Site:	Prostate
Medical Record #:	MR 000000	Tumor Collection Date:	MM/DD/YYYY
Client Accession #:	CA 000000	Normal Collection Date:	MM/DD/YYYY
Ordering Physician:	Sample Physician	Received Date:	MM/DD/YYYY

Results Snapshot
Analytes sequenced: DNA+RNA
Actionable Targets: 3
TMB: Low
MSI: Stable
Clinical Trials: Yes

Diagnosis: **Adenocarcinoma of prostate**

KEY BIOMARKER FINDINGS

KEY BIOMARKERS	FDA-APPROVED DRUGS -for patient's cancer[1]	FDA-APPROVED DRUGS -for another cancer[1]	DRUGS PREDICTED NON-BENEFICIAL/ REDUCED BENEFIT	POTENTIAL CLINICAL TRIALS
AXIN (G665fs)				Yes
GEN1 (M44fs)				Yes
PALB2[2] (A935fs)	olaparib, talazoparib + enzalutamide	niraparib + abiraterone, olaparib + abiraterone, rucaparib, talazoparib		Yes
TUMOR MUTATION BURDEN (TMB)				
LOW (2 mut/Mb)				No
MICROSATELLITE STATUS (MSI)				
STABLE				No

HIGH INTEREST BIOMARKERS

As part of the OncoExTra test, key biomarkers relevant in the patient's tumor type have been assessed: ***NTRK1, NTRK2, NTRK3, RET, BRAF, ATM, ATR, BRCA1, BRCA2, BARD1, BRIP1, CDK12, CHEK1, CHEK2, FANCA, FANCL, MLH1, MRE11A, NBN, PALB2, RAD51B, RAD51C, RAD51D, RAD54L****. If clinically pertinent event(s) in these biomarkers have been identified, the biomarker(s) will appear within the 'Key Biomarker Findings' section of the report. If Biomarkers from this list do not appear, clinically pertinent event(s) have not been identified or fell outside of the OncoExTra reporting thresholds (please see Disclaimer Limitations information).*

ADDITIONAL SIGNIFICANT ALTERATIONS	
CUX1 (R1007*)	No
ZFHX3 (G699fs)	No

[1]The prescribing information for the FDA-approved therapeutic option may not include the associated Key Biomarker.

Reporting that's easy to interpret and easy to access

1. Mutations and fusions associated with FDA-approved treatments‡
2. Immuno-oncology signatures (TMB/MSI)
3. Clinical trial options
4. High Interest Biomarkers

Provider portal:

Results delivered to you within 14 days of receiving both samples via a secure and convenient online portal[7]

Get the full genomic story with a spotlight on what matters most. To order, visit OncoExTra.com/order

Reference: 1. American Cancer Society. Cancer Facts & Figures 2024. Atlanta: *American Cancer Society*; 2024. **2.** Nombela P, et al. BRCA2 and Other DDR Genes in Prostate Cancer. *Cancers.* 2019;11(3), p.352. **3.** Shore N, et al. *Future Oncol.* 2021;17(22):2907-2921. **4.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines ®) for Prostate Cancer V.4.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed May 17, 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. **5.** SEER Cancer Stat Facts: Prostate Cancer. National Cancer Institute. Bethesda, MD, https://seer.cancer.gov/statfacts/html/prost.html. **6.** Rushin Patel et al., Efficacy of PARP inhibitors in patients with metastatic castration resistant prostate carcinoma: A meta-analysis of phase III randomized controlled trials.. *JCO 41*, e17060-e17060(2023). **7.** White T, Szelinger S, LoBello J, et al. Analytic validation and clinical utilization of the comprehensive genomic profiling test, GEM ExTra™. *Oncotarget*. 2021;12:726-739.
‡The OncoExTra test was developed, and the performance characteristics validated by Genomic Health, Inc., a wholly-owned subsidiary of Exact Sciences Corporation following College of American Pathologists (CAP) and Clinical Laboratory Improvement Amendments (CLIA) regulations. The OncoExTra test is performed at the Genomic Health Phoenix clinical laboratory. Exact Sciences clinical laboratories are accredited by CAP, certified under CLIA regulations, and qualified to perform high-complexity clinical laboratory testing. This tests has not been cleared or approved by the US Food and Drug Administration or other notified regulatory authority.

OncoExTra has been validated according to the guidelines set forth by the New York State Department of Health. Whole exome (DNA) events have been validated to include point mutations, indels, and copy number alterations, as well as MSI analysis and TMB calculation. Whole transcriptome (RNA) has been validated to report on select fusion genes and special transcripts

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