oncoExTra®

by EXACT SCIENCES®

Biomarker testing for all solid tumors that are advanced, metastatic, unresponsive to treatment, recurrent, rare, or aggressive

Understanding your test results

It's important for you and your doctor to understand what may be driving your cancer. Biomarker testing identifies the alterations in your tumor cells that is causing them to grow abnormally. The OncoExTra® test provides detections of the biomarkers in your tumor, as well as the treatment options that may be most appropriate for you.

Biomarkers (or tumor genomic alterations) detected in your tumor.

This shows which biomarkers and therapies are being studied. Links in the later pages of the report lead to study details. You and your doctor can review to determine if a clinical trial may be right for you.

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oncoExTra®
Tissue Genomic Profiling

Results for Sample Patient

Date of birth: MM/DD/YYYY
Sex at birth: Female
Medical record #: MR-000000
Client accession #: CA-0000000
Diagnosis: Lung Cancer

Normal collection date: MM/DD/YYYY
Tumor collection date: MM/DD/YYYY
Specimen type: FFPE Block
Specimen site: Lung
Tumor content: 20%

Ordering provider: Sample Physician
Health care office: Cancer Center
Order ID: WF00008824
Received date: MM/DD/YYYY
Report date: MM/DD/YYYY

Biomarkers with therapy associations

Analytes tested: DNA, RNA, Protein
Clinical trials available: Yes, see page 6 for details

Tumor mutation burden (TMB): Intermediate (8 mut/Mb)
Microsatellite status (MSI): Stable

Biomarker details	Associated therapies	Level of evidence[1]	Analyte
CD74::ROS1 (Fusion)	**Possible benefit:** crizotinib, entrectinib, lorlatinib, repotrectinib, taletrectinib	A	RNA
	ceritinib	C	
	cabozantinib	D	
NF1 (Q369*) VAF: 19%	**Possible benefit:** trametinib	D	DNA
PD-L1 (22C3) (Low) TPS: 1-4	**Possible benefit:** atezolizumab, atezolizumab + bevacizumab, durvalumab, nivolumab + ipilimumab, pembrolizumab	A	Protein
	nivolumab	B	
	avelumab, dostarlimab-gxly, retifanlimab-dlwr, tislelizumab, toripalimab	C	

[1] Level of evidence classification: Level A - FDA-approved or included in guidelines for patient's tumor type; Level B - strong evidence from clinical studies; Level C - FDA-approved for another tumor type or moderate evidence from clinical studies; Level D - case reports.

Tumor-specific biomarkers with no actionable alterations

ALK, BRAF, EGFR, ERBB2, KRAS, MET, NRG1, NTRK1, NTRK2, NTRK3, RET

Notes

*NOTE: The CD74::ROS1 fusion was detected at both the RNA level and as a structural translocation at the DNA level in the sample. The CD74::ROS1 fusion event is reported in the Biomarkers with therapy associations section of the report, and the structural translocation at the DNA level of the same is listed in the Variants of Unknown Significance section to avoid repetition of contents related to therapy and clinical trials.

**NOTE: Contraindications for treatment with certain PD-1/PD-L1 inhibitors may include presence of some oncogenic drivers (i.e., ALK, RET or ROS1 rearrangements, EGFR exon 19 deletion or L858R), which has been shown to lower response rates (PMID: 27225694, 31125062). Targeted therapy for an oncogenic driver should take precedence over treatment with an immune checkpoint inhibitor per clinical guidelines for NSCLC.

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Another data point that helps inform your doctor if an immunotherapy might be right for you.

Therapies that may work for your tumor.

Shows the results of any immunohistochemistry (IHC) tests that your doctor may have also ordered. IHC tests look for cancer related proteins which may also inform your treatment options.†

These are relevant biomarkers that were not detected.

In this example of a lung cancer patient, the OncoExTra test detected 2 alterations listed in the column at the left. These alterations (CD74/ROS1 and NF1) have a number of therapies that may be beneficial, and both alterations have associated clinical trials. In addition, the PD-L1 immunohistochemistry (IHC) test indicates another 11 possible therapies.

† IHC testing is not currently available in New York State

The OncoExTra test is not an FDA-cleared or approved IVD device or companion diagnostic for the referenced biomarkers and FDA approved therapies.

The OncoExTra® test is designed for all advanced solid tumor cancers.

Below are some of the most prevalent cancer types and some of the associated biomarkers that are important for treatment decisions.

Lung

EGFR · ALK · ROS1 · BRAF · NTRK · MET · NRG1 · RET · KRAS · ERBB2 · TMB · MSI · PD-L1

Breast

BRCA · PIK3CA · NTRK · ERBB2 · RET · BRAF · ESR1 · AKT1 · PTEN · TMB · MSI · PD-L1

Colon

KRAS · NRAS · BRAF · NTRK · ERBB2 · RET · TMB · MSI · PD-L1

Bladder

FGFR · NTRK · RET · BRAF · ERBB2 · TMB · MSI · PD-L1

To learn more about the OncoExTra test
OncoExtra.com/patientinfo

To learn about insurance coverage
OncoExTra.com/coverage

Covered by MEDICARE

The OncoExTra test 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.

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 test has not been cleared or approved by the US Food and Drug Administration.

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