



9-12 day
TAT*

ALL SOLID TUMORS

OmniSeq[®] INSIGHT

Make confident treatment decisions
based on the entire tumor profile



All components of the OmniSeq INSIGHT test are fully resulted on greater than 93% of completed cases.



FFPE tissue**

- Resection specimens
- Needle core biopsies
- Cell blocks from FNA**

OmniSeq® INSIGHT

Pan-solid tumor profiling

Analyzing a single tumor biopsy with advanced DNA and RNA next-generation sequencing (NGS) technology, OmniSeq INSIGHT can identify treatment options in **one comprehensive, easy-to-read report.**

Identify approved drug candidates

Comprehensive genomics

- Identifies genomic alterations in 523 genes
- Fusions/splice variants using RNA-Seq hybrid capture
- Coverage of clinical practice guideline-recommended biomarkers across solid tumor types

Immunotherapy eligibility

Comprehensive immune profiling

- PD-L1 IHC**
- MSI & TMB** profiling
- Immune biomarker drug targets

Eligible clinical trials

List of patient-eligible clinical trials within 200 miles of patient's physical address¹

- Testing for biomarkers with clinical trial associations

The result report includes:

- A summary page of marker findings, including pertinent negatives
- Therapy considerations section with treatment setting, approval status and multi-marker associations
- Flags potential cancer-associated hereditary variants

PATIENT

TUMOR TYPE: Non-Small Cell Lung Carcinoma

REPORT DATE: []

ORDER ID: []

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PATIENT

DIAGNOSIS C34.90, Malignant neoplasm of unsp part of unsp bronchus or lung, Stage IV

NAME: []

DOB: []

MRN: []

ORDER ID: []

REPORT DATE: []

SPECIMEN

FACILITY ID: []

SOURCE: []

COLLECTION DATE: []

RECEIVED DATE: []

CLIENT

ORDERING PROVIDER: []

PROVIDER FACILITY: []

ORDERING FACILITY: []

OmniSeq Clinical Support
For questions or to discuss results:
1-800-781-1259
MedOncSupport@labcorp.com

OmniSeq INSIGHT™ interrogates 523 genes by next generation sequencing for mutations, select copy number alterations, HLA Class I genotypes and fusions/splice variants including genes associated with homologous recombination repair deficiency (HRR/HRD), microsatellite instability (MSI) and tumor mutational burden (TMB), expression of 64 immune genes, and PD-L1 by immunohistochemistry (IHC).
See last page of report for all tested markers.

MARKER FINDINGS

See MARKER OF TAIL S for additional information

SNV /Indel	EGFR E746_A750del (exon 19 del) TP53 R175G
Fusion	No positive findings.
Copy Gain	AKT2 gain ERBB2 gain
Copy Loss	No positive findings.
See APPENDIX for variants of unknown significance (VUS)	
Signatures	Tumor Mutation Burden (TMB): 10.1 mut/Mb (High) Microsatellite Instability (MSI): MS-Stable
Immune Markers	PD-L1 IHC (22C3): Tumor Proportion Score <1% (Negative) Immune Gene Expression by RNA Sequencing in Clinical Trials: BTLA, CTLA4, NY-ESO-1, TIGFB1, TLR8, VISTA HLA Class I: A*24:02, 11:01 B*46:01, 40:10 C*01:02, 04:03
Note: PD-L1 is measured by immunohistochemistry (IHC) and RNA-expression profiling, and HLA Class I genotyping using next generation sequencing. See APPENDIX for additional details.	
PERTINENT NEGATIVE GENOMIC VARIANTS	
FDA or NCCN guideline indicated variants for this tumor type tested but NOT detected.	
ALK G1202R	EGFR exon 19 ins MET gain
ALK fusion	EGFR exon 20 ins NTRK1/2/3 fusion
BRAF V600E	HER2 (ERBB2) mut RET fusion
EGFR (L858R, S768I, L861Q, Codon 719)	KRAS mut ROS1 fusion
EGFR T790M	MET exon 14 skip

COMMENTS

Pathologist: No pathologist comments.

Testing: All testing was completed.

Potential Germline Variants: Consider genetic counseling if an inherited cancer syndrome is suspected

TP53 R175G

OmniSeq INSIGHT is performed at OmniSeq, Inc., 700 Ellicott Street, Buffalo NY 14203 | 1 (800) 781-1259 | CLIA ID: 33D2098748 | CAP #9405346
Signed by Eric Severson at RS-001, Shakti Ramkissoon, MD, Medical Director 09/27/24 18:33 PM EDT

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p.1/23

A consolidated assay for two different treatment paradigms:



Genomic profiling

- 523-gene NGS panel
- MSI and TMB
- DNA and RNA sequencing
- SNVs, indels, CNAs and fusions**
- Interrogation of full coding regions
- HLA genotyping**



Immune profiling

- PD-L1 IHC
- 64 RNA expression/immune profiling genes by immune cycle step:
 - T-cell priming/trafficking
 - T-cell recognition
 - T-cell infiltration
 - Killing cancer cells
 - Cancer testis antigens

Why choose OmniSeq INSIGHT?

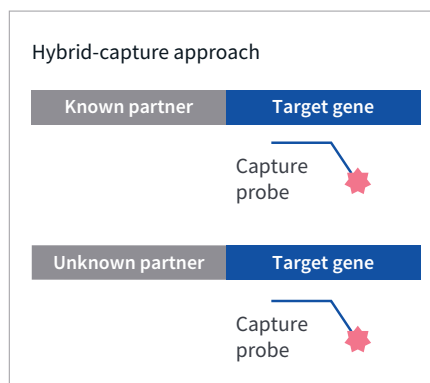
- Genes aligned with FDA approvals, professional practice guidelines and clinical trials
- HRR/HRD-related genes for PARP therapeutic selection**
- Full coding region coverage for each gene, which improves variant detection compared to “hotspot” testing strategies
- An RNA-seq hybrid capture approach that allows for the detection of common and novel fusions
- Targeting of unique emerging and actionable markers
- Immune gene expression (mRNA) analysis to evaluate the interaction between the tumor and its microenvironment
- HLA genotyping to identify HLA Class I alleles at HLA-A, HLA-B and HLA-C genes

When to consider OmniSeq INSIGHT:

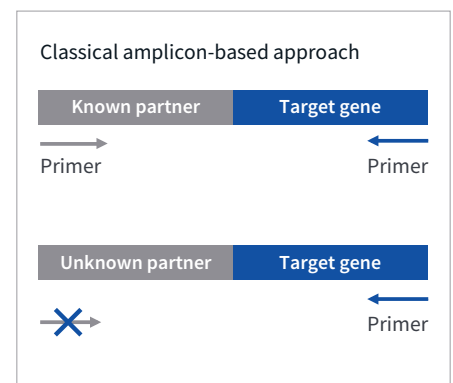
- For patients with advanced and recurrent cancer when evidence-based guidelines recommend broad genomic profiling for evaluation of alterations to guide targeted therapy
- When considering clinical trials as an option for treatment and a patient’s unique genomic and/or immune profile facilitates enrollment
- When a cancer lacks an effective standard-of-care therapy or when a tumor is poorly differentiated and of uncertain origin
- When relapse or disease progression has occurred after prior therapies
- Use of HLA genotype as a biomarker for patient inclusion in immunotherapeutic clinical trials requires MHC** Class I status

OmniSeq INSIGHT delivers the distinct advantage of leveraging three NGS technologies, leading to the highest quality results:²

- DNA sequencing to detect SNVs, indels, CNAs, TMB and MSI
- RNA sequencing by hybrid-capture to detect known and unknown fusion partners
- RNA gene expression profiling provides novel, differentiating insights into the tumor immune microenvironment



Identifies both known and unknown fusion partners



This approach fails to identify unknown fusion partners

Sample requirements (include pathology report)

Formalin-fixed paraffin embedded (FFPE) tissue

- Resection specimens
- Needle core biopsies
- Cell blocks from fine needle aspirates (FNAs)

****Do not submit decalcified specimens, cytology smears or samples from hematologic malignancies****

FFPE block (preferred) or 20 unbaked, positively charged, unstained slides cut at 5 µm plus one H&E.

Proven expertise in FFPE sample processing

A proprietary pre-analytical FFPE extraction process maximizes our ability to yield DNA and RNA sequencing data from limited specimens.



Labcorp's high laboratory quality standards

- NYS CLEP approved
- ISO 13485:2016 and ISO 15189:2012
- CLIA and CAP accredited



Labcorp's broad national coverage

- In-network with most major health plans
- 1,600 contractual relationships with plans, payers and other healthcare organizations

Powering better decisions

When you need trusted information to make clear, better health decisions, consider us your source for oncology testing. Whether you are advancing therapies through clinical trials or diagnosing and treating individuals with cancer, we know you are working relentlessly to improve patient outcomes. We can help.

Result reporting

Turnaround time of 9-12 days.

Extensive managed care contracts

Help patients maximize their benefits.

Genetic counseling

A national network of genetic counselors to help inform and support your patients. Call us at 855-GC-CALLS or 855-422-2557.

Call us

Arizona: 800-710-1800

Connecticut: 800-447-5816

North Carolina: 800-345-4363

Tennessee: 800-874-8532

Schedule a pickup

Toll-free (within the US) at 866-875-2271

Visit us

oncology.labcorp.com

References

1. OmniSeq Bioinformatics Knowledgebase - data curation September 2022.
2. Conroy JM, et. al., A scalable high-throughput targeted next-generation sequencing assay for comprehensive genomic profiling of solid tumors. *PLoS One*. 2021 Dec 2;16(12):e0260089.

*Turnaround time is reported based on the number of days from sample receipt in the lab to release of clinical report

**FFPE: Formalin-fixed paraffin embedded; FNA: Fine-needle aspiration; IHC: immunohistochemistry; MSI: Microsatellite instability; TMB: Tumor mutational burden; SNVs: Single-nucleotide variants; Indels: Insertions/deletions; CNAs: Copy number alterations; HLA: Human leukocyte antigen; HRR: Homologous recombination repair; HRD: Homologous recombination deficiency; MHC: Major histocompatibility complex; PARP: Poly-ADP ribose polymerase

For more information about OmniSeq INSIGHT visit oncology.labcorp.com/omniseq, or contact your Labcorp Oncology sales representative.

