ALL SOLID TUMORS

OmniSeq INSIGHT℠

Make confident treatment decisions
based on the entire tumor profile

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OmniSeq INSIGHT℠
A single, comprehensive report that provides treatment options for your patient.

The patient report delivers complete INSIGHT into the tumor and its microenvironment by summarizing FDA-approved therapies, immunotherapies and eligible clinical trials for your patient's solid tumor.

From a single tumor biopsy, analyzed by advanced NGS technology, OmniSeq INSIGHT identifies treatment options in **one comprehensive, easy-to-read report**.

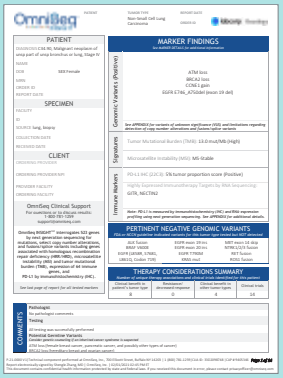
FFPE tissue
- Resection specimens
- Needle core biopsies
- Cell blocks from FNA

- Multiplex DNA and RNA NGS platform
- Protein expression (PD-L1)

Identify approved drug candidates
Comprehensive genomics
- Identifies genomic alterations in 523 genes
- Fusions/splice variants using RNA-Seq hybrid capture
- Coverage of NCCN® guideline-recommended biomarkers across solid tumor types

Immunotherapy eligibility
Comprehensive immune profiling
- PD-L1 immunohistochemistry (IHC)
- MSI & TMB profiling*
- Immune biomarker drug targets

Eligible clinical trials
List of patient-eligible clinical trials within 200 miles of patient's physical address[1]
- Testing for biomarkers with clinical trial associations



The result report includes:
- A summary page of marker findings
- A therapy considerations section with treatment setting, approval status and multi-marker associations
- Flagged potential cancer-associated hereditary variants

OmniSeq INSIGHT was developed by OmniSeq® and is performed by OmniSeq as a send-out from Labcorp Oncology, its U.S. distributor.

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

Immune profiling

- PD-L1 immunohistochemistry (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?

INSIGHT is the only comprehensive test to contain all of the following:

- 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 which 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

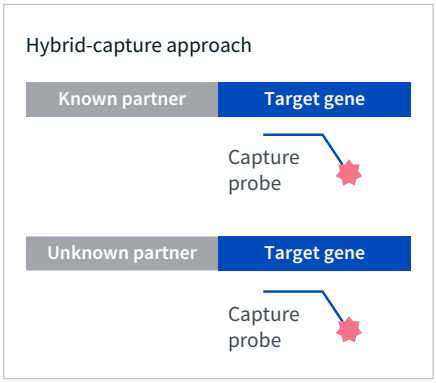
When to consider OmniSeq INSIGHT:

INSIGHT may be useful as a tool in various clinical settings, including:

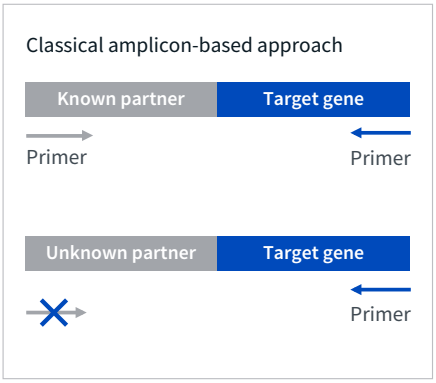
- When guidelines recommend broad genomic profiling to evaluate genes with clinical evidence and therapeutic recommendations or when standard biomarker evaluation yields no targeted therapeutic option
- When a broad genomic profile identifies treatment options in clinical trials including immunotherapies and targeted therapies for patient enrollment
- When a cancer lacks an effective standard-of-care therapy at the time of diagnosis or when a tumor is poorly differentiated and of uncertain origin
- When relapse or disease progression has occurred after prior therapies

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

- 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 microenvironment



Identifies both known and unknown fusion partners



This approach fails to identify unknown fusion partners

*MSI – microsatellite instability; TMB – tumor mutational burden; SNVs – single nucleotide variants; indels – insertions/deletions; CNAs – copy number alterations; HRR – homologous recombination repair; HRD – homologous recombination deficiency; PARP – poly-ADP ribose polymerase;

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 specimen.

OmniSeq® high laboratory quality standards

- NYS CLEP approved
- ISO 13485 (2016) certified
- CLIA and CAP accredited

Labcorp broad national coverage

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

References

1. OmniSeq Bioinformatics Knowledgebase - data curation January 2021.

Powering better decisions

When you need trusted information to make clear, better health decisions, consider us your source for oncology. 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.

Results reporting
Turnaround time of 12-14 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

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

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