ALL SOLID TUMORS

OmniSeq INSIGHT®

Make confident treatment decisions
based on the entire tumor profile

labcorp | Oncology

OmniSeq INSIGHT®

Pan-solid tumor profiling

Using NGS technology, OmniSeq INSIGHT evaluates genomic alterations and immune-related biomarkers within a patient's tumor.

The report delivers a comprehensive summary of FDA-approved therapies, immunotherapies and eligible clinical trials for your patient's solid tumor.

From a single tumor biopsy, analyzed by advanced DNA and RNA 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 clinical practice guideline--recommended biomarkers across solid tumor types

Immunotherapy eligibility

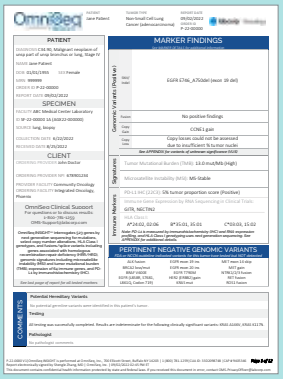
Comprehensive immune profiling

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

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 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
- HLA genotyping to identify HLA Class I alleles at HLA-A, HLA-B, and HLA-C genes

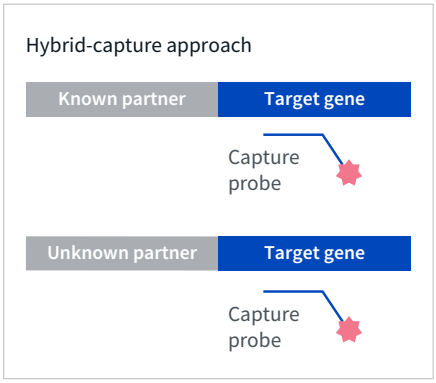
When to consider OmniSeq INSIGHT:

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

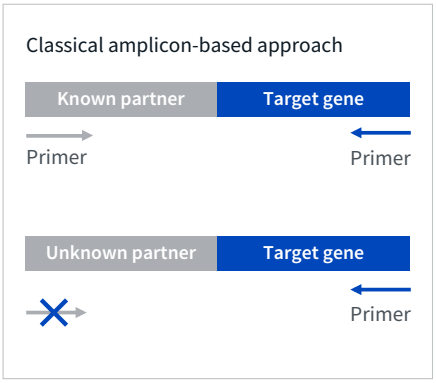
- For patients with advanced and recurrent cancer when evidence-based guidelines recommend broad genomic profiling for evaluation of alterations to guide targeted therapy
- When considering clinical trials as an option for treatment and a patient’s unique genomic and/or immune profile facilitates enrollment
- 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 requiring 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

*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 specimens.

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 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.

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