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Neuberg DIAGNOSTICS | CENTER FOR GENOMIC MEDICINE

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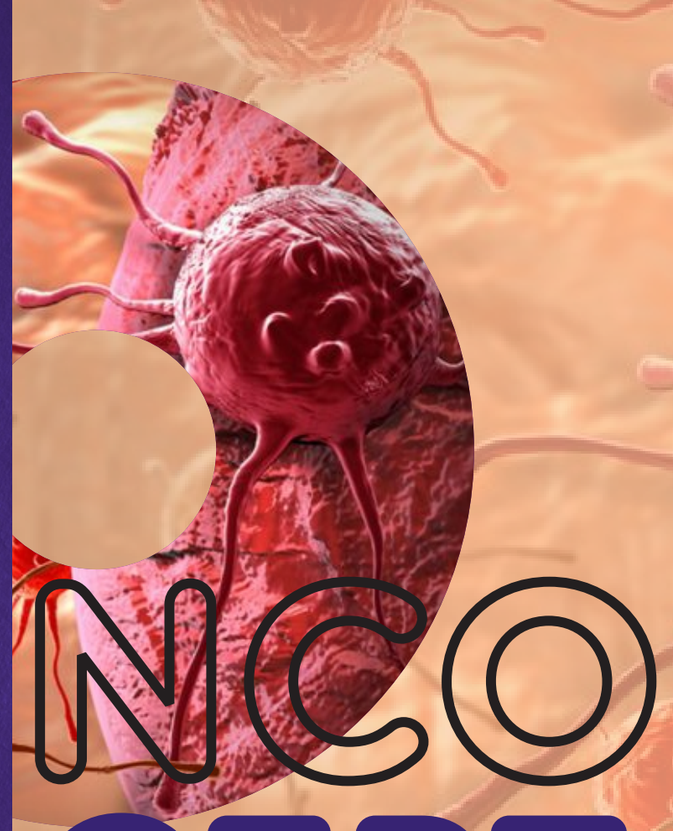
GENOMIC TESTING OF CANCERS



NCOCEPT

SOLID & LIQUID

GENOMIC TESTING OF CANCERS

Cancer is caused by a change in cellular DNA, called mutations. Using genomic tests, we read and analyze important parts of tumor genome that reveal important characteristics of cancer. This analysis finds (1) Targeted therapies applicable for the patient, (2) Immunotherapies, (3) Prognosis of the disease and (4) In identification of clinical trials for patient enrollment. Genomic testing of tumor provides clinically actionable insight to oncologists.

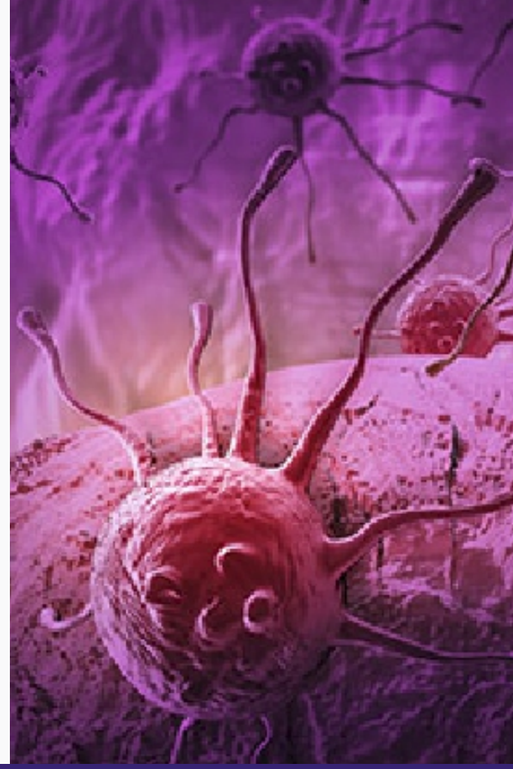
OncoCEPT Solid

Cancer is disease of the genome. Changes in genome or mutations lead to uncontrolled growth of cells and hence into tumors. While cancers are characterized by numerous genomic aberrations, some of these somatic mutations, known as driver mutations, induce growth and impaired differentiation leading to cancer development. Various consortia such as The Cancer Genome Atlas (TCGA), International Cancer Genome Consortium (ICGC) and such have sorted and identified driver mutations in various different cancers, based on studies of thousands of tumor tissues. Various targeted therapies are developed against the specific mutations that drive the cancer tumor.

OncoCEPT Solid identifies these driver mutations and helps in identifying targeted therapies, prognosis and clinical trials applicable to the patient.

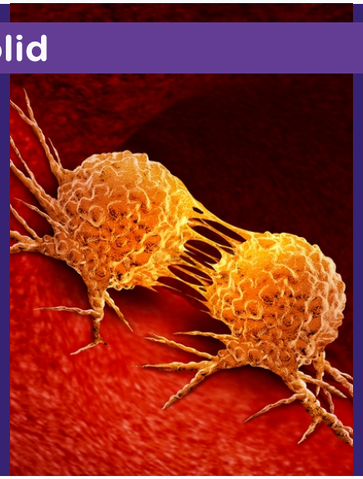
OncoCEPT Liquid

- OncoCEPT Liquid is non- invasive approach to cancer as it analyses the circulating tumor DNA from a blood sample especially for lung and breast cancer patients.
- It can be used as a tool to detect treatment resistance to targeted therapies.
- To check the heterogeneity of the disease, or during/after treatment to check for acquired resistance mutations.
- To monitoring cancer progression.Cancer also evolves over time. It may relapse after treatment of primary tumor. This relapse occurs due to changes in its genome.
- OncoCEPT Liquid cangive snapshots of evolving cancer genome when thetest is performed at periodic intervals.
- This information can help the oncologist pre-empt and modify traetment regimen.



Prominent Technical Features of OncoCEPT Solid

- Enables the detection of variants in 52 key solid tumor genes. These genes are well characterized in the published literature and associated with oncology drugs that are FDA approved, part of National Comprehensive Cancer Network (NCCN) guidelines, or in clinical trials.
- The assay allows concurrent analysis of DNA and RNA.
- Simultaneously detect multiple types of variants, including hotspots, single nucleotide variants (SNVs), indels, CNVs, and gene fusions, in a single workflow.
- Uses formalin-fixed, paraffin embedded (FFPE) tissues, fine-needle aspirates, fresh tissues as starting sample.
- Turn around time (TAT): 10 business days.



Prominent Technical Features of OncoCEPT Liquid

- Detection of somatic mutations in plasma, down to a level of 0.1% in genes relevant to solid tumors.
- Analysis of single nucleotide variants, short indels, copy number variations, and fusions that are frequently mutated in research cancer samples.
- 150 hotspots in 11 genes focused on solid tumors, are analyzed.
- Sample type: whole blood.
- Turn around time (TAT): 10 business days.

Microsatellite Instability (MSI)

In normal cells, the DNA mismatch repair (MMR) system recognizes and repairs genetic mismatches generated during DNA replication. A deficient MMR (dMMR) system results in the persistence of DNA mismatches in microsatellites that may then be incorporated into the genetic code as mutations which is sporadic in nature. Tumors that are deficient of DNA mismatch repair (MMR) system are designated as MSI-high and the once with intact MMR are called MSI-stable.

Pembrolizumab is indicated for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H). These tumors are (1) Solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or (2) colorectal cancer that has progressed following treatment with fluoropyrimidine, oxaliplatin, and irinotecan.

Prominent Technical Features of MSI Test

- Turn around time (TAT): 7 days
- Five microsatellite regions are analyzed.

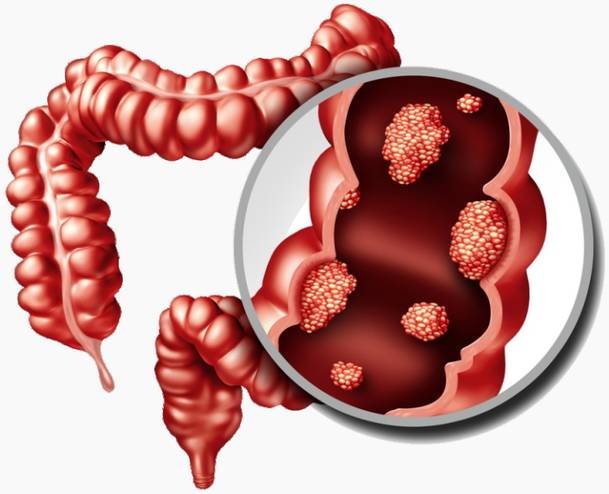
Lung Cancer

There are two main classifications of lung cancer: small cell lung cancer and non-small cell lung cancer (NSCLC). Both types of cancers are treated differently.NSCLC begins in the epithelial cells. Adenocarcinoma starts in cells that produce mucus. Squamous cell carcinoma begins in the cells that line the airways. Large cell carcinoma begins in cells other than the two types described above.

There are multiple genes that may be changed, called mutations, in a lung tumor that drive the cancer. These mutations are not inherited or passed down to children instead they are restricted only to the patient. Mutations that are known to drive lung cancer may occur on one or more of several genes, including EGFR, ALK, KRAS, BRAF, HER2, ROS1, and RET. Testing the tumor for all these genes can be done by MSI and OncoCEPT-Solid.

AGENT	TARGET(S)	FDA-APPROVED INDICATION(S)	AGENT
AgentAfatinib (Gilotrif)	EGFR (HER1/ERBB1), HER2 (ERBB2/neu)	Non-small cell lung cancer (with EGFR exon 19 deletions or exon 21 substitution (L858R) mutations	Afatinib (Gilotrif)
Alectinib (Alecensa)	ALK	Non-small cell lung cancer (with ALK fusion)	Alectinib (Alecensa)
Atezolizumab (Tecentriq)	PD-L1	Urothelial carcinoma Non-small cell lung cancerfusion)	Atezolizumab (Tecentriq)
Brigatinib (Alunbrig)	ALK	Non-small cell lung cancer (ALK+)	Brigatinib (Alunbrig)
Ceritinib (Zykadia)	ALK	Non-small cell lung cancer (with ALK fusion)	Ceritinib (Zykadia)
Crizotinib (Xalkori)	ALK, MET, ROS1	Non-small cell lung cancer (with ALK fusion or ROS1 gene alteration)	Crizotinib (Xalkori)
Dabrafenib (Tafinlar)	BRAF	Non-small cell lung cancer (with BRAF V600E mutations)	Dabrafenib (Tafinlar)
Erlotinib (Tarceva)	EGFR (HER1/ERBB1)	Non-small cell lung cancer (with EGFR exon 19 deletions or exon 21 substitution (L858R) mutation)	Erlotinib (Tarceva)
Gefitinib (Iressa)	EGFR (HER1/ERBB1)	Non-small cell lung cancer (with EGFR exon 19 deletions or exon 21 substitution (L858R) mutations)	Gefitinib (Iressa)
Necitumumab (Portrazza)	EGFR (HER1/ERBB1)	Squamous non-small cell lung cancer	Necitumumab (Portrazza)
Osimertinib (Tagrisso)	EGFR	Non-small cell lung cancer (with EGFR T790M mutation)	Osimertinib (Tagrisso)
Trametinib (Mekinist)	MEK	Non-small cell lung cancer (with BRAF V600E mutation)	Trametinib (Mekinist)

Colorectal Cancer



Colorectal cancer begins in healthy cells of colon or rectum lining.It grows into large mass called tumor. A tumor can be cancerous or benign. A cancerous tumor is malignant when it grows to other parts of the body. These changes usually take years to develop. Both genetic and environmental factors can cause the changes.

Multiple techniques are used to diagnose and treat colorectal cancers. Molecular tests are performed to identify specific genes, proteins, and other factors which drive the tumor. Metastatic or recurrent colorectal cancer is preferred for testing. Results of these tests will help decide whether the treatment options include a type of treatment called targeted therapy.Below is the list of genes that have clinical significance in management of colorectal cancer patients. These genes are analyzed using tests: Microsatellite instability (MSI), OncoCEPT- Solid.

AGENT	TARGET(S)	FDA-APPROVED INDICATION(S)	AGENT
Cetuximab (Erbitux)	EGFR (HER1/ERBB1)	Colorectal cancer (KRAS, NRAS, BRAF wild type)	Cetuximab (Erbitux)
Nivolumab (Opdivo)	PD-1	Colorectal cancer (MSI-H)	Nivolumab (Opdivo)
Panitumumab (Vectibix)	EGFR (HER1/ERBB1)	Colorectal cancer (KRAS, NRAS, BRAF wild type)	Panitumumab (Vectibix)
Pembrolizumab (Keytruda)	PD-1	Colorectal cancer (MSI-H)	Pembrolizumab (Keytruda)

Breast Cancer

Breast cancer can be invasive or noninvasive. Invasive breast cancer spreads into surrounding tissues. Noninvasive breast cancer does not go beyond the milk ducts or lobules in the breast. Most breast cancers start in the ducts or lobes and are called ductal carcinoma or lobular carcinoma. Breast cancers can also be divided into three large subtypes based on the biomarkers they express. These are Hormone receptor-positive, Her2 positive and triple negative breast cancer.

HORMONE RECEPTOR-POSITIVE: Breast cancers expressing estrogen receptors (ER) and/or progesterone receptors (PR) are called “hormone receptor-positive.About 60% to 75% of breast cancers have estrogen and/or progesterone receptors.

HER2 POSITIVE: About 15% to 20% of breast cancers depend on the gene called human epidermal growth factor receptor 2 (HER2) to grow.HER2-positive breast cancers grow more quickly. They can also be either hormone receptor-positive or hormone receptor-negative.

TRIPLE NEGATIVE: Tumor that does not express ER, PR, or HER2, the tumor is called triple-negative.Triple-negative cancer is also more common in women with a mutation in the BRCA1 or BRCA2 genes. Guidelines require triple-negative breast cancer patients younger than 60yrs to be tested for BRCA gene mutations.

Below is the list of genes that have clinical significance in management of breast cancer patients. These genes are analyzed using tests: Microsatellite instability (MSI), OncoCEPT- Solid.

AGENT	TARGET(S)	FDA-APPROVED INDICATION(S)	AGENT
Adotrastuzumabem-tansine (Kadcyla)	HER2 (ERBB2/neu)	Breast cancer (HER2+)	Adotrastuzumabem-tansine (Kadcyla)
Everolimus (Afinitor)	mTOR	Breast cancer (HR+, HER2-)	Everolimus (Afinitor)
Lapatinib (Tykerb)	HER2 (ERBB2/neu), EGFR (HER1/ERBB1)	Breast cancer (HER2+)	Lapatinib (Tykerb)
Neratinib (Nerlynx)	HER2 (ERBB2/neu)	Breast cancer (HER2 overexpressed/ amplified)	Neratinib (Nerlynx)
Palbociclib (Ibrance)	CDK4, CDK6	Breast cancer (HR+, HER2-)	Palbociclib (Ibrance)
Pertuzumab (Perjeta)	HER2 (ERBB2/neu)	Breast cancer (HER2+)	Pertuzumab (Perjeta)
Ribociclib (Kisqali)	CDK4, CDK6	Breast cancer (HR+, HER2-)	Ribociclib (Kisqali)