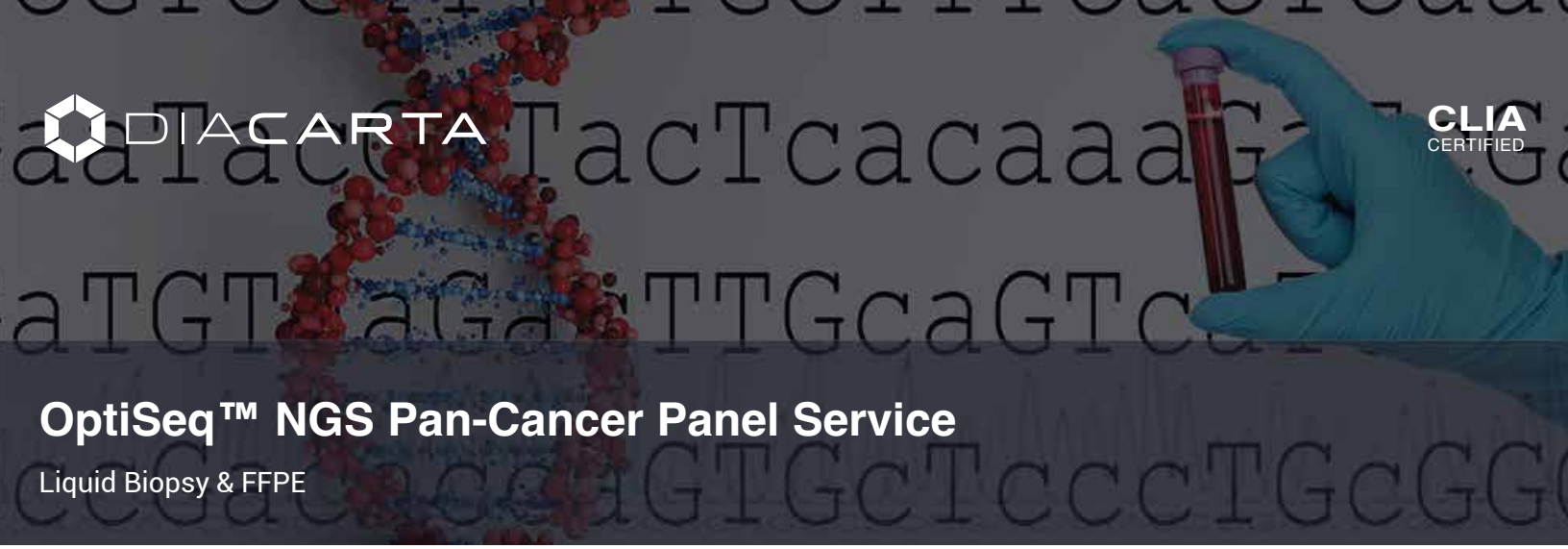


DIACARTA

CLIA CERTIFIED

OptiSeq™ NGS Pan-Cancer Panel Service

Liquid Biopsy & FFPE

Highlights

- **Samples Tested**
  Liquid biopsy (blood/cfDNA) and FFPE samples (tissue/DNA)
- **CLIA Certified**
  Laboratory developed tests performed in a CLIA certified laboratory
- **Rapid**
  Sample receipt to clinical report within 10 days. No deep sequencing needed
- **Highly Sensitive**
  As low as 1% variant allele frequency (VAF) detection
- **Extremely Uniform**
  100% observed uniformity at ≥ 0.2x mean depth and 97% observed uniformity at ≥ 0.5x
- **Low DNA Input Needed**
  10 ng for detection of somatic mutations (SNP); 100 pg for germline mutations
- **Report to Clinicians**
  Comprehensive clinically significant variants, FDA approved therapies and clinical trials

Introduction

DiaCarta offers a sample-to-report OptiSeq™ Targeted Sequencing cancer diagnostic service at its state-of-art CLIA certified facility. Our comprehensive OptiSeq™ Pan-Cancer Panel test enables oncologists to learn accurate and actionable information and helps match advanced cancer patients to approved targeted therapies in addition to drugs in clinical trials. The liquid biopsy/FFPE sample prep workflow provides clients with fast turnaround time and accurate VAF detection process. Powered by Qiagen's Clinical Insight Interpret software suite, variants are classified based on guidelines with the focus on actionable content from drug labels and clinical trials. Information is presented in a final clinical report. The whole process from blood/FFPE sample to clinical report is guaranteed to be completed within 10 business.

OptiSeq™ Pan-Cancer Panel - A Blood based Test

From 2 vials of blood, the OptiSeq™ test digitally sequences billions of genomic data points while avoiding the painful, risky and cost of a tissue biopsy. It allows for accurate detection of cancer mutations, effectively provides potential treatment options for patients and their doctors and can be used to as a recurrence monitoring tool to manage cancer progress.

Stay in control of your patient's cancer management with a highly sensitive, accurate and effective sequencing service.

DiaCarta currently offers a comprehensive OptiSeq™ pan-cancer panel in a CLIA laboratory. It is designed to target 2,900 commonly observed mutational positions (hotspots) from 65 oncogenes and tumor suppressor genes. This panel contains a single pool of 601 primer pairs and the average amplicon length is 145 bp – perfectly suitable for cell-free DNA and FFPE DNA sequencing.

OptiSeq™ Pan-Cancer Gene Panel (65 Genes)

ABL1	AKT1	ALK	APC	ATM	BRAF	BRCA1	BRCA2	CDH1
CDKN2A	CSF1R	CTNNB1	DDR2	DNMT3A	EGFR	ERBB2	ERBB3	ERBB4
EZH2	FBXW7	FGFR1	FGFR2	FGFR3	FLT3	FOXL2	GNA11	GNAQ
GNAS	HNF1A	HRAS	IDH1	IDH2	JAK2	JAK3	KDR	KIT
KRAS	MAP2K1	MET	MLH1	MPL	MSH6	MTOR	NF1	NF2
NOTCH1	NPM1	NRAS	PDGFRA	PIK3CA	PIK3R1	PTCH1	PTEN	PTPN11
RB1	RET	SMAD4	SMARCB1	SMO	SRC	STK11	TERT	TP53
TSC1	VHL							

Streamlined Workflow

Step 1: Sample Receipt and Preparation
Collect and send 'Sample' to DiaCarta. Extract DNA from received samples

Step 2: Library Preparation & QC
Multiplex PCR based library construction and QC. No need for ligation, end repair, DNA fragmentation, overnight hybridization, or microfluidic devices

Step 3: Sequencing Run
NGS targeted sequencing. No need for deep sequencing

Step 4: Data Analysis
Performed and approved by DiaCarta's Medical Director

Step 5: Report
Clinical report ready within 10 days

Sample Clinical Report

Patients Information
Patient Name: Jane Smith
Sex: Female
DOB: November 10, 1969
Patient ID: 0000001
Reason for Referral: Melanoma
Note: Per outside report '"48 years old female with reported clinical history of melanoma"

Physician Information
Ordering Physician: John Adams
Account Number: 0000002
Account: 2178 First Street, Birmingham, AL 35296
Phone: 123-456-789
Fax: 123-456-788
Email: jadams@jadams.com

Speciman Information
Speciman Type: Whole Blood Streck Tubes, cfDND
Collection Date: May 29, 2017
Received Date: May 29, 2017
Report Date: June 4, 2017

Result: Positive

Summary of Clinically Significant Variants and Associated Treatment

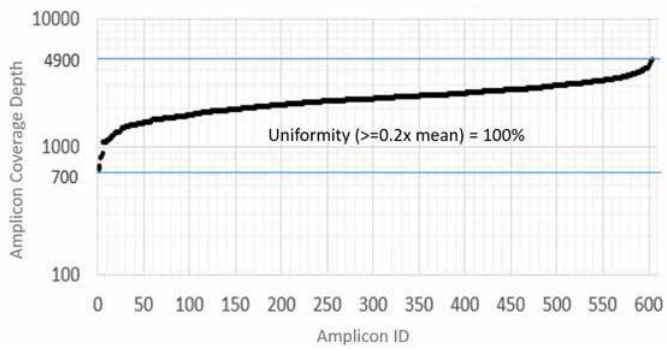
Variants Reported	Allele Fraction	FDA Approved Therapies for Indication	FDA Approved Therapies for Other Indications	Therapies Associated with Resistance	Potential Clinical Trials
BRCA2 p.S2701P	1.96%	No relevant therapies	Tamoxifen Anthracycline/ Chemotherapy Platinum agent Cisplatin/Gemcitabine ...	Olaparib	No recruiting clinical trials identified
EGFR c.*282_ *284delAAA	3.82%	No relevant therapies	Erlotinib Afatinib/Cetuximab Gefitinib EGFR TKIs ...	Erlotinib Gefitinib Alectinib Ceritinib ...	No recruiting clinical trials identified
NF1 p.P678fs*10	1.3%	No relevant therapies	No relevant therapies	No relevant therapies	6 potential trials
NF1 p.K2547fs*9	1.36%	No relevant therapies	No relevant therapies	No relevant therapies	6 potential trials
NF1 c.7552+40delA	1.38%	No relevant therapies	No relevant therapies	No relevant therapies	No recruiting clinical trials identified

...

DiaCarta's clinical report also includes information regarding variant details, FDA approved therapies for this indication, therapies associated with resistance, clinical trials, genes tested, methods and limitations and selected citations.

OptiSeq™ Pan-Cancer Gene Panel Uniformity

The unique multiplex PCR buffer system and strong primer design capability ensure optimal coverage uniformity for target amplicons. For the OptiSeq™ Pan-Cancer Gene Panel, we have consistently observed 100% uniformity (at ≥ 0.2x mean depth) and 97% uniformity (at ≥ 0.5x mean depth).



Specifications

Specification	OptiSeq™ Pan-Cancer Panel
Service Certification	Service performed in a CLIA Certified Laboratory
Sample Type	Liquid biopsy (blood/cfDNA) and FFPE samples (tissue/DNA)
Species	Human
Recommended DNA Input (Amount)	10 ng for detection of somatic mutations (SNP); 100 pg for germline mutations
Sequencing Platform	Illumina Sequencers (MiniSeq, MiSeq, NextSeq, Hiseq)
Enrichment Method	Multiplex PCR
Number of Primer Pools	1
Number of Primer Pairs	601
Number of Target Genes	65
Target Region Size (bp)	55199
Amplicon Size	Average 146 bp (from 125-175 bp)
Sample Multiplexing (at ~2000x mean coverage)	Miseq 2×150 Read Length: ~25 samples NextSeq Series Mid Output 2×150 Read Length: ~200 NextSeq Series High Output @ 2×150 Read Length: ~600
Coverage Uniformity (at ≥ 0.2x mean coverage)	>95%
On-target Reads % (% reads aligned to target regions out of total aligned reads)	>95%
Turnaround time	Sample receipt to clinical report within 10 days

OptiSeq™ Research-Use-Only Validated Gene Panel

Lung Cancer Panel (29 Gene)

AKT1	ALK	BRAF	CCND1	CTNNB1	DDR2	EGFR	EIF1AX	ERBB2
FGFR2	FGFR3	GNAS	HRAS	IDH1	IDH2	KIT	KRAS	MAP2K1
MDM2	MET	NRAS	PDGFRA	PIK3CA	PTEN	RET	ROS1	STK11
TP53	TSHB							

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To order, please email order@diacarta.com or call 1-800-246-8878
To learn more, please visit http://www.diacarta.com/services/ngs/

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