indivumed services
A CROWN BIOSCIENCE Company

Product Profile Services

Mutation Profiling of Biobank Samples Using Next Generation Sequencing

Overview

Indivumed Services has been perfecting it´s high-quality research network for over a decade, allowing for the accumulation of more than 25,000 patient cases within the company´s ISO-certified cancer biobank. Currently, our biobank contains thousands of discrete samples and data sets secured and available for research. A standardized ischemia time-controlled biospecimen collection comprises of fresh frozen (FF) and formalin-fixed paraffin-embedded (FFPE) tumor and corresponding normal tissue samples as well as serum, plasma, PBMC´s and urine. Furthermore, the comprehensive clinical data collection of each patient includes pathology report data, patient and family history, medication, clinical chemistry, and biospecimen collection information such as exact tissue ischemia times.

Next Generation Sequencing

We offer Next Generation Sequencing capabilities, giving you giving the option to purchase already characterized samples or to screen our biobank tissues to determine presence or absence of mutated genes.

Mutation profiling is performed with Illumina´s TruSeq Amplicon Cancer Panel that detects somatic mutations in the following 48 cancer-related genes by multiplexed targeted resequencing.

Analysis of somatic mutations in 48 caner-related genes

ABL1	CDH1	ERBB4	GNA11	JAK2	MLH1	PIK3CA	SMARCB1
AKT1	CDKN2A	FBXW7	GNAQ	JAK3	MPL	PTEN	SMO
ALK	CSF1R	FGFR1	GNAS	KDR	NOTCH1	PTPN11	SRC
APC	CTNNB1	FGFR2	HNF1A	KIT	NPM1	RB1	STK11
ATM	EGFR	FGFR3	HRAS	KRAS	NRAS	RET	TP53
BRAF	ERBB2	FLT3	IDH1	MET	PDGFRA	SMAD4	VHL

Indivumed Services Mutation Profiling Workflow

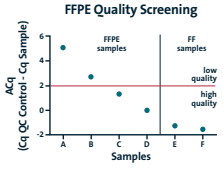
FF or FFPE samples can be used for mutation profiling. Routinely, Indivumed Services performs sequencing on FF tumor samples.

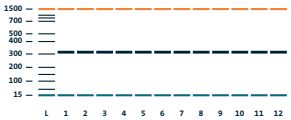
gDNA Isolation
Quantification and qualification of DNA

Library Preparation
Library preparation control

Sequencing on MiSeqDx
Sequencing run and data processing

Data Analysis
Annotation, filtering and reporting

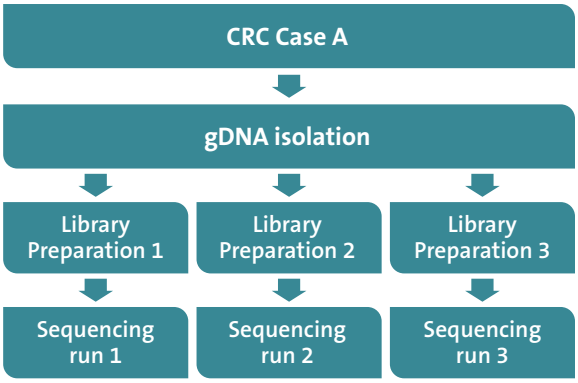


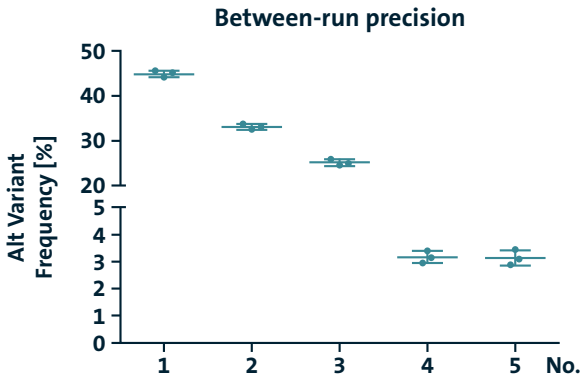


CRC case A, Tumor Content 60%				
Gene	COSMIC ID	DNA	Protein	Variant (%)
APC	COSMIC ID	c.2626C>T	p.R876*	31.4
ATM	COSM18852	c.2572T>C	p.F858L	86.4
KRAS	COSM1360827	c.743G>A	p.R248Q	22.9
TP53	COSM10662	c.437C>T	p.A146V	65.4

Validation — Between-Run Precision

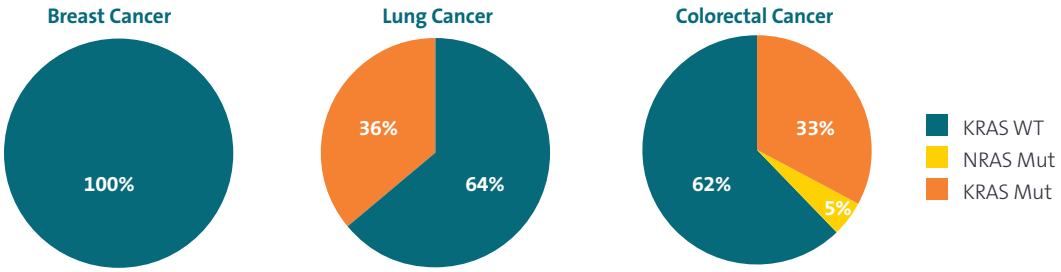
Our service includes highly qualified method establishment and validation. In the example below, between-run precision is analyzed by performing three library preparations and sequencing runs of the same sample. The frequency of the alternative variant (mutant) in comparison to the reference allel (wildtype) is shown for five different variants. The calculated coefficients of correlation are below 10 %.





Distribution of RAS Mutations

We offer characterized breast, lung as well as colorectal cancer samples. As an example, diagrams represent different frequencies of RAS mutations in breast, lung and colorectal cancer patients.



Distribution of RAS Mutations

- Pre-analytical controlled tumor tissue
- Fresh Frozen and FFPE tumor and matched normal tissue
- Serum, plasma, PBMC's and urine sample sets of each case
- Rigorous ISO-certified collection, processing and storage
- Comprehensive clinical data including follow up
- Characterized samples by Next Generation Sequencing
- Screening of your Indivumed Services biobank purchase with Illumina's TruSeq Amplicon Cancer Panel

About Indivumed Services

Indivumed Services, a Crown Bioscience Company, is a global contract research organization (CRO) that offers an industry-leading oncology biobank and a range of service platforms to advance oncology and immuno-oncology drug discovery and development.

Holding a unique biobank of clinical specimens, unrivalled in quality and associated clinical history, which currently totals almost one million patient samples, the company partners with extensive clinical network of more than 60 entities in the United States, Europe, and Asia providing direct and controlled access to relevant surgical biospecimens and blood samples.

Further known for their enhanced immunohistochemistry and spatial transcriptomics, Indivumed Services' platforms complement a range of established Crown Bioscience capabilities supporting biomarker discovery.

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