celldx™

Deep genomic analysis of tumor

BETTER

FASTER

ECONOMICAL

DATAR CANCER GENETICS

UNITED KINGDOM | GERMANY | INDIA

SNVs INDELs CNAs Fusions TMB PDL1 MSI HRR

celldx™

celldx™

provides deep genomic analysis for patient with advanced cancer.

Targeted Therapy: Evaluation of companian diagnostic indications for targeted therapy selection.

Immunotherapy: Helps inform immunotherapy decisions by including genomic signatures such as Microsatellite Instability (MSI), Tumor Mutational Burden (TMB) and PD-L1 status (TPS and/or CPS status of Dako 22C3 and 28-8). Additional PD-L1 SP142 for NSCLC and Urothelial cancer.

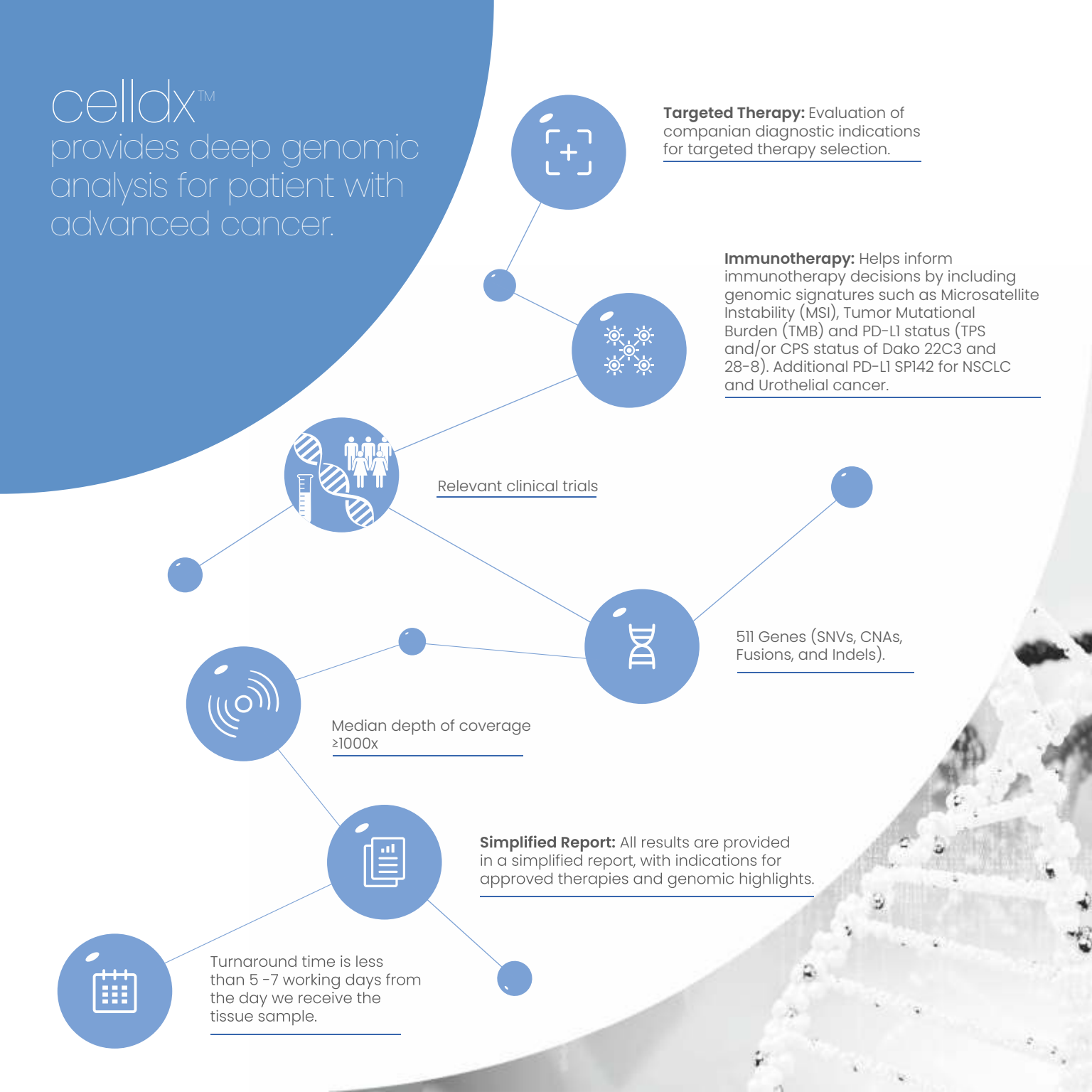
Relevant clinical trials

511 Genes (SNVs, CNAs, Fusions, and Indels).

Median depth of coverage ≥1000x

Simplified Report: All results are provided in a simplified report, with indications for approved therapies and genomic highlights.

Turnaround time is less than 5 -7 working days from the day we receive the tissue sample.

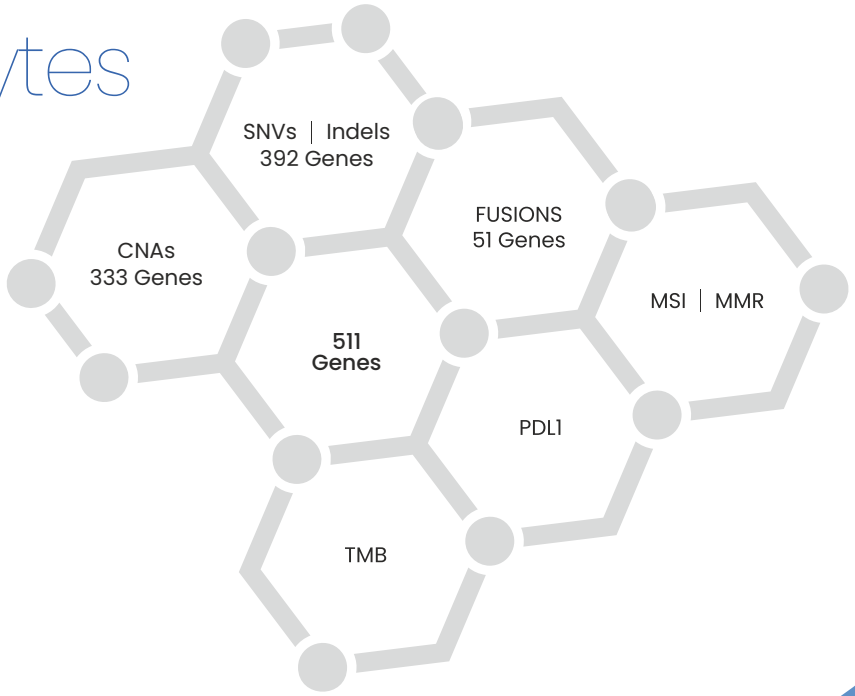


About celldx™

Credible and Dependable

celldx™ is a Next-Generation Sequencing based in-vitro diagnostic test that simultaneously detects various genomic alterations such as single nucleotide variants (SNVs), short insertions and deletions (InDels), copy number alterations (CNAs), fusions/rearragements, tumor mutation burden (TMB), microsatelite instability((MSI)) and PD-L1 status.

Analytes



SNVs: Single-Nucleotide Variants
Indels: Insertions and Deletions
CNAs: Copy Number Alteration
MSI: Microsatellite Instability
MMR: Mismatch Repair
PDL1: Programmed Death-Ligand 1
TMB: Tumor Mutational Burden

Biomarker-based drug indications

INDICATIONS	BIOMARKER	US FDA-APPROVED THERAPY
Non-Small Cell Lung Cancer (NSCLC)	EGFR exon 19 deletions/ exon 21 L858R	Gefitinib, Erlotinib, Afatinib, Dacomitinib Osimertinib
	EGFR exon 20 insertion	Amivantamab, Mobocertinib
	EGFR T790M	Osimertinib
	KRAS G12C	Sotorasib
	ALK rearrangements	Alectinib, Crizotinib, Ceritinib, Lorlatinib, Brigatinib
	BRAF V600E	Dabrafenib in combination with Trametinib
	ROS1 rearrangements	Entrectinib, Crizotinib
	RET rearrangements	Selpercatinib, Pralsetinib
	MET exon 14 skipping alterations	Capmatinib, Tepotinib
	NTRK1/2/3 fusions	Larotrectinib, Entrectinib
	PD-L1	Pembrolizumab, Nivolumab, Atezolizumab
Colorectal Cancer (CRC)	KRAS wild-type	Cetuximab, Panitumumab
	MSI-H/dMMR	Nivolumab ± Ipilimumab or Pembrolizumab
	BRAF V600E	Encorafenib
Breast Cancer	ERBB2 (HER2) amplification	Lapatinib, Neratinib, Trastuzumab , Ado-trastuzumab emtansine, Pertuzumab, Margetuximab, Tucatinib, Fam-trastuzumab deruxtecan
	BRCA1/2 alterations	Olaparib, Talazoparib
	PIK3CA	Alpelisib

Biomarker-based drug indications

INDICATIONS	BIOMARKER	US FDA-APPROVED THERAPY
Ovarian Cancer	BRCA1/2 alterations	Olaparib, Rucaparib, Niraparib
	HRR deficient tumors	Niraparib
Melanoma	BRAF V600E	Dabrafenib or Vemurafenib
	BRAF V600E or V600K	Trametinib or Cobimetinib in combination with Dabrafenib or Vemurafenib
Urothelial Carcinoma	FGFR2, FGFR3 alterations	Erdafitinib
	PD-L1	Pembrolizumab, Atezolizumab
Gastric or GE junction adenocarcinoma	ERBB2 (HER2) amplification	Trastuzumab, Fam-Trastuzumab deruxtecan
Cholangiocarcinoma	FGFR2 (fusion/rearrangement)	Infigratinib, Pemigatinib
	IDH1 Mutations	Ivosidenib
Pancreatic Cancer	BRCA1/2 mutation	Olaparib
Prostate Cancer	HRR deficient tumors, BRCA1/2 mutations	Olaparib
Thyroid Cancer	RET Fusions	Selpercatinib, Pralsetinib
Solid Tumors	NTRK1/2/3 fusions	Entrectinib, Larotrectinib
	MSI-H/dMMR	Pembrolizumab

Sample : FFPE Block with Tumor content $\geq$ 5% or 10 Unstained slides

Gene list

SNVs / Indels / CNAs

ABCB1	ABL1	ABL2	ABRAXAS1	ACVR1*	ACVR1B	ACVR2A	ADAMTS12	ADAMTS2	AKT1
AKT2	AKT3	ALK	AMER1	APC	AR	ARAF	ARHGAP35	ARID1A	ARID1B
ARID2	ARID5B	ASXL1	ASXL2	ATM	ATP1A1*	ATR	ATRX	AURKA	AURKC
AXIN1	AXIN2	AXL	B2M	BAP1	BARD1	BCL2	BCL2L12	BCL6	BCOR
BCR*	BLM	BMP5*	BMPR2	BRAF	BRCA1	BRCA2	BRIP1	BTK*	CACNA1D*
CALR*	CARD11	CASP8	CBFB	CBL	CCND1	CCND2	CCND3	CCNE1	CD274
CD276	CD79B*	CDC73	CDH1	CDH10	CDK12	CDK4	CDK6	CDKN1A	CDKN1B
CDKN2A	CDKN2B	CDKN2C	CHD4	CHEK1	CHEK2	CIC	CIITA*	CREBBP	CSF1R*
CSMD3	CTCF	CTLA4	CTNNB1*	CTNND2	CUL1*	CUL3	CUL4A	CUL4B	CYLD
CYP2C9	CYP2D6*	CYSLTR2*	DAXX	DDR1	DDR2	DDX3X	DGCR8*	DICER1	DNMT3A
DOCK3	DPYD	DROSHA*	DSC1	DSC3	E2F1*	EGFR	EIF1AX	ELF3	EMSY
ENO1	EP300	EPAS1*	EPCAM	EPHA2	ERAP1	ERAP2	ERBB2	ERBB3	ERBB4
ERCC2	ERCC4	ERCC5*	ERRFI1	ESR1	ETV6	EZH2	FAM135B	FANCA	FANCC
FANCD2	FANCE	FANCF	FANCG	FANCI	FANCL	FANCM	FAS*	FAT1	FBXW7
FGF19	FGF23	FGF3	FGF4	FGF7*	FGF9	FGFR1	FGFR2	FGFR3	FGFR4
FLT3	FLT4	FOXA1	FOXL2*	FOXO1*	FUBP1	FYN	GATA2	GATA3	GLI1*
GLI3	GNA11*	GNA13	GNAQ*	GNAS	GPS2	H3F3A	H3F3B	HDAC2	HDAC9
HIF1A*	HIST1H2BD*	HIST1H3B*	HLA-A	HLA-B	HNF1A	HRAS*	ID3*	IDH1*	IDH2
IGF1R	IKBKB	IL6ST*	IL7R	INPP4B	IRF4*	IRS4*	JAK1	JAK2	JAK3
KDM5C	KDM6A	KDR	KEAP1	KIT	KLF4*	KLF5	KLHL13*	KMT2A	KMT2B
KMT2C	KMT2D	KNSTRN*	KRAS	LARP4B	LATS1	LATS2	MAGOH	MAP2K1	MAP2K2*
MAP2K4	MAP2K7	MAP3K1	MAP3K4	MAPK1	MAPK8	MAX	MCL1	MDM2	MDM4
MECOM	MED12*	MEF2B	MEN1	MET	MGA	MITF	MLH1	MLH3	MPL
MRE11	MSH2	MSH3	MSH6	MTAP	MTOR	MTUS2*	MUTYH	MYC	MYCL
MYCN	MYD88	MYOD1*	NBN	NCOR1	NF1	NF2	NFE2L2	NOTCH1	NOTCH2
NOTCH3	NOTCH4	NRAS	NSD2*	NT5C2*	NTRK1	NTRK2*	NTRK3	NUP93*	PALB2
PARP1	PARP2	PARP3	PARP4	PAX5*	PBRM1	PCBP1	PDCD1	PDCD1LG2	PDGFRA
PDGFRB	PDIA3	PGD	PHF6	PIK3C2B	PIK3CA	PIK3CB	PIK3CD*	PIK3CG*	PIK3R1
PIK3R2	PIM1	PLCG1	PMS1	PMS2	POLD1	POLE	POT1	PPM1D	PPP2R1A

Gene list

SNVs / Indels / CNAs

PPP2R2A	PPP6C	PRDM1	PRDM9	PRKACA	PRKAR1A	PSMB10*	PSMB8*	PSMB9*	PTCH1
PTEN	PTPN11	PTPRD*	PTPRT	PXDNL	RAC1	RAD50	RAD51	RAD51B	RAD51C
RAD51D	RAD52	RAD54L	RAF1	RARA	RASA1	RASA2	RB1	RBM10	RECQL4
RET	RGS7*	RHEB	RHOA*	RICTOR	RIT1	RNASEH2A	RNASEH2B	RNASEH2C*	RNF43
ROS1	RPA1	RPL10*	RPL22*	RPL5*	RPS6KB1	RPTOR	RUNX1	RUNX1T1*	SDHA
SDHB	SDHC*	SDHD	SETBP1	SETD2	SF3B1	SIX1*	SIX2*	SLCO1B3	SLX4
SMAD2	SMAD4	SMARCA4	SMARCB1	SMC1A	SMO	SNCAIP*	SOCS1*	SOS1*	SOX2*
SOX9	SPEN	SPOP	SRC	SRSF2*	STAG2	STAT1*	STAT3	STAT5B*	STAT6
STK11	SUFU	TAF1*	TAP1	TAP2	TBX3	TCF7L2	TERT	TET2	TGFBR1*
TGFBR2	TMEM132D*	TNFAIP3	TNFRSF14	TOP1	TP53	TP63	TPMT	TPP2	TRRAP*
TSC1	TSC2	TSHR*	U2AF1	UGT1A1*	USP8	USP9X	VHL	WAS*	WT1
XPO1	XRCC2	XRCC3	YAP1	YES1	ZBTB20*	ZFHX3	ZMYM3	ZNF217	ZNF429
ZRSR2									

Fusion

AKT2	ALK	AR	AXL	BRAF	BRCA1	BRCA2	CDKN2A	EGFR	ERBB2
ERBB4	ERG	ESR1	ETV1	ETV4	ETV5	FGFR1	FGFR2	FGFR3	FGR
FLT3	JAK2	KRAS	MDM4	MET	MYB	MYBL1	NF1	NOTCH1	NOTCH4
NRG1	NTRK1	NTRK2	NTRK3	NUTM1	PDGFRA	PDGFRB	PIK3CA	PPARG	PRKACA
PRKACB	PTEN	RAD51B	RAF1	RB1	RELA	RET	ROS1	RSPO2	RSPO3
TERT									

* NO CNA

DATAR CANCER GENETICS

UNITED KINGDOM | GERMANY | INDIA

Accreditations for Our Lab in India

CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS

CLIA
Accredited Laboratory
No.: 99D2171983

ilac-MRA

MC-4586

ISO 27001:2013

ISO 9001:2015

CE IVD

EC REP

Advena Ltd. Tower Business Centre, 2nd Flr.,
Tower Street, Swatar, BKR 4013,Malta

Contact us:

✉ **UK**: enquiries@datarpgx.com • **Germany**: info-eu@datarpgx.com • **India**: response@datarpgx.com

datarpgx.com

R6 | Apr 15, 2022