celldx™

Deep genomic analysis of solid tumours

Nordic Laboratories®

For professional use only

About celldx™

celldx™ is a tissue based comprehensive molecular profiling of solid tumours with the aim to personalise therapy options. celldx™ also provides information on the benefit of immune checkpoint inhibitors.

To individualise the cancer treatment, celldx™ detects genetic alterations suited for the application of targeted therapies. In addition, immunostaining is performed on the provided tissue samples for PD-L1 suitability in combination with tumour mutational burden and MSI|MMR.

celldx™ is performed at our state of the art laboratories which are ISO 15189, CLIA and CAP as well as UKAS accredited.

celldx™ provides molecular analysis for patients with advanced cancer.

SNVs | INDELs 392 Genes	**CNAs 333 Genes**	**Fusions 51 Genes**
TMB | PDL1	**511 Genes**	**MSI | MMR**

celldx™ provides advantages whenever ...

... there has to be a fast decision about a targeted therapy.

... an immunotherapy is an option for the patient.

SNV = Single nucleotid variation
INDEL = Insertion / Deletion
CNA = Copy number alteration
MSI = Micro satellite instability
MMR = Mismatch repair

Comprehensive celldx™

Examples for 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) amplifikation	Lapatinib, Neratinib, Trastuzumab, Ado-Trastuzumab emtansine, Pertuzumab, Margetuximab, Tucatinib, Fam-Trastuzumab deruxtecan
	BRCA1/2 alterations	Olaparib, Talazoparib
	PIK3CA	Alpelisib
Ovarian Cancer	BRCA1/2 alterations	Olaparib, Rucaparib, Niraparib
	HRR deficient tumours	Niraparib
Melanoma	BRAF V600E	Dabrafenib or Vemurafenib
	BRAF V600E oder 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) amplifikation	Trastuzumab, Fam-Trastuzumab deruxtecan
Cholangliocarcinoma	FGFR2 (fusion/rearrangement)	Ivosidenib
	IDH1 mutations	Olaparib
Pancreatic Cancer	BRCA1/2 mutation	Olaparib
Prostate Cancer	HRR deficient tumours, BRCA1/2 mutations	Olaparib
Thyroid Cancer	RET fusions	Selpercatinib, Pralsetinib
Solid Tumours	NTRK1/2/3 fusions	Entrectinib, Larotrectinib
	MSI-H/sMMR	Pembrolizumab

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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	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									

Sample requirements

Sample requirements:
- FFPE block with at least 5% tumour content or 10 unstained slides

Turn Around Time (TAT):
- Analysis based on fresh tissue – 10 working days from receipt of the sample

FAQ‘s

How long does it take to receive the results and how will they be provided?
The turnaround time, after which the patient or his treating doctor will receive the results, is usually 10 working days from the day the laboratory receives the tissue sample. The test report contains all genomic highlights and lists the particular therapy options.

Which analytes are included?
SNVs, INDELs, CNAs, Fusions, TMB, PD-L1, MSI, MMR, HRD (Homologous recombination deficiency).

Is celldx™ suited as a companion diagnostic tool?
Yes, celldx™ can provide information if a target alteration is present. Evaluation of therapies in the need of companion diagnostics across several cancer indications is available as well as clinical trial matching across all solid tumours.

Is celldx™ of advantage when selecting an immunotherapy?
celldx™ provides informed decisions if an immunotherapy is beneficial using genomic signatures like microsatellite instability (MSI), tumor mutational burden (TMB) and PD-L1 status via immunostaining.

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Publication

Akolkar D, Patil D, Srivastava N, Patil R et al. (2021) Development and validation of a multigene variant profiling assay to guide targeted and immuno therapy selection in solid tumors. PLoS ONE 16(2): e0246048. https://doi.org/10.1371/journal.pone.0246048.

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Nordic Laboratories

Nordic Laboratories
Nordic Laboratories
@nordiclaboratories
Nordic Laboratories & dnalife

Head Office:
Nygade 6, 3.sal
1164 Copenhagen K
Denmark
Tlf: +45 33 75 10 00

South Africa Office:
North Block, Thrupps Centre
204 Oxford Rd, Illove 2196
South Africa
Tel: +27 (0) 11 268 0268

UK Office:
11 Old Factory Buildings, Stonegate
East Sussex, TN5 7DU
United Kingdom
Tel: +44 (0)1580 201 687

info@nordic-labs.com
www.nordic-labs.com