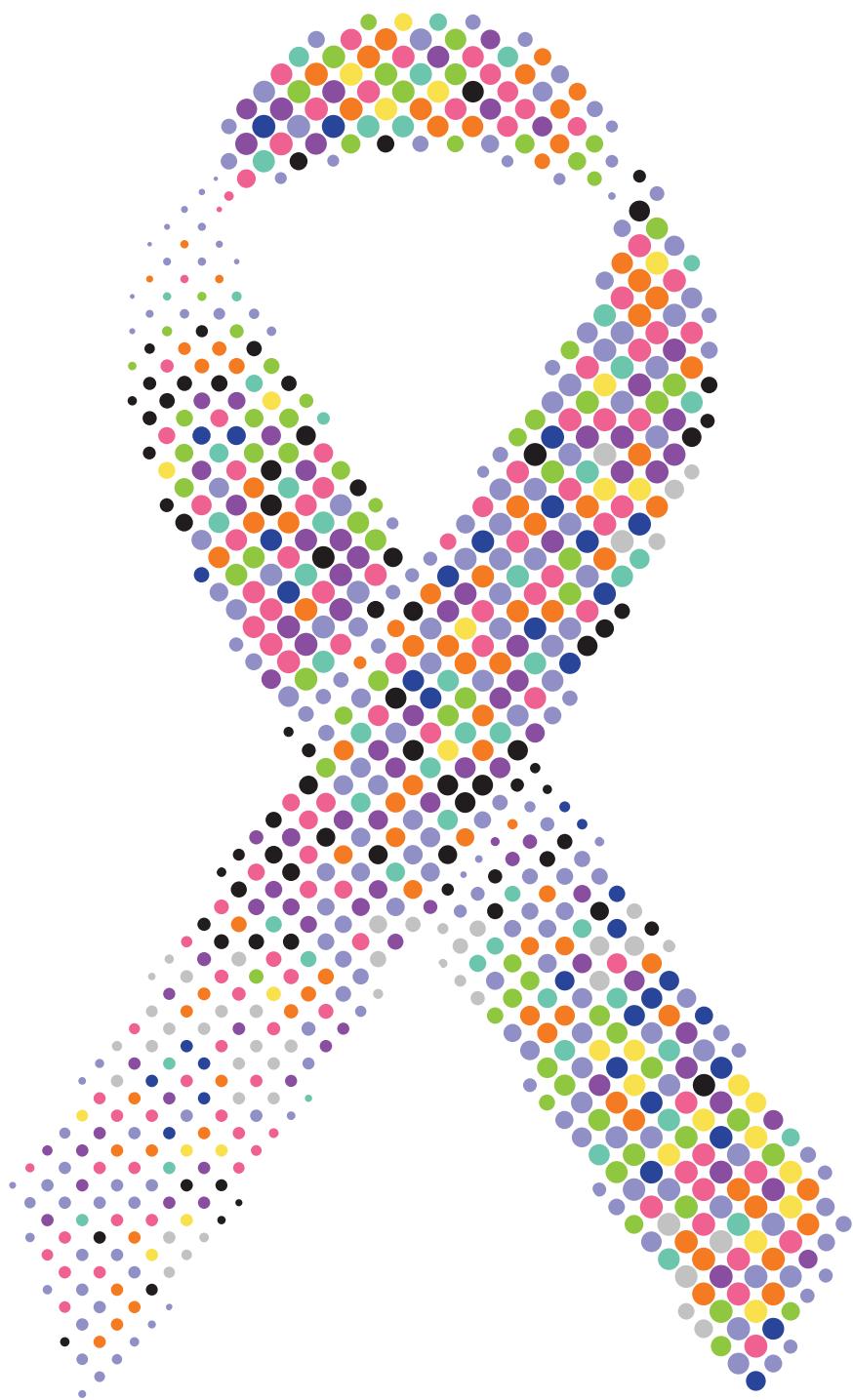


Comprehensive tumor gene panel



Description

The Comprehensive tumor panel (170 genes) is a targeted next generation sequencing (NGS) assay that simultaneously detects mutations

SNVs & Short-Indels



Fusions and Splice Variants



Genes Amplifications



Comprehensive tumor panel



Lung



Breast



Ovarian



Prostate



Gastrointestinal Stromal Tumor



Thyroid



Colorectal



Melanoma



Bladder



Uterine



Pancreatic



Hepatocellular
Carcinomas



Sarcomas



Thymus



Glioma

Test details

Test Code	Test Name	Specimen Requirements	TAT (days)
MGM549	Comprehensive tumor panel (170 genes)	FFPE tissue block with 10% tumor content (as verified by our in-house pathologist)	21 working days

Benefits of the comprehensive tumor panel

- Internally validated as an accurate and cost-effective method to identify mutations, fusions and amplifications across numerous genes known to be associated with response or resistance to specific targeted therapies
- Enables determination of most appropriate targeted therapy for each patient with solid tumor based on genomic profile of their disease
- Assessment of prognosis and guiding treatment for patients with solid tumors at baseline as well as at disease progression/recurrence

In-house validation

- The median sequencing depth of this panel is $\geq 250X$
- The panel can detect SNVs, Short-Indels and fusions, as low as 5% mutant allele frequency in the background of wild type allele
- On 100+ clinical samples, reference standards and cell lines: The sensitivity, specificity, and accuracy to detect SNVs, Short-Indels and fusions are as mentioned below

Sample type	Mutation type	Sensitivity	Specificity	Accuracy	Limit of detection
Reference Standards (Horizon Diagnostics)/- Cell lines/ Clinical samples	SNV/ Short-Indels (<20 bp)	100%	100%	100%	$\geq 5\%$
	Fusion	95%	100%	100%	NA
	Copy Number Variations	100%	100%	100%	$\geq 5\%$

Highlights of clinical report

- We follow good laboratory practice (GLP) and good clinical practice (GCP) in our process and reporting.
- High throughput NGS data analysis, curation and interpretation of the mutations and fusions are performed by well-trained clinical scientist/genome analysts and cancer genome experts.
- Report provides clinically significant alterations and its interpretations, their associations with drug efficacy, recommended targeted therapies/possible mechanisms of resistance, prognosis and available active clinical trials, and supporting medical evidences from large clinical studies that can guide the oncologists in making treatment decisions.
- Clinical reporting and interpretations are based on the international guidelines: ASCO, AMP, CAP, NCCN and ESMO.

Table 1: The panels detects mutations (SNVs and Short Indels), amplifications, fusions and splice variants in the following genes:

SNVs and Short Indels (<20bp) (from DNA)									
AKT1	BRIP1	CREBBP	FANCI	FGFR2	JAK3	MSH3	PALB2	RAD51D	TSC1
AKT2	BTK	CSF1R	FANCL	FGFR3	KDR	MSH6	PDGFRA	RAD54L	TSC2
AKT3	CARD11	CTNNB1	FBXW7	FGFR4	KIT	MTOR	PDGFRB	RB1	VHL
ALK	CCND1	DDR2	FGF1	FLT1	KMT2A(MLL)	MUTYH	PIK3CA	RET	XRCC2
APC	CCND2	DNMT3A	FGF2	FLT3	KRAS	MYC	PIK3CB	RICTOR	
AR	CCNE1	EGFR	FGF3	FOXL2	MAP2K1	MYCL1	PIK3CD	ROS1	
ARID1A	CD79A	EP300	FGF4	GEN1	MAP2K2	MYCN	PIK3CG	RPS6KB1	
ATM	CD79B	ERBB2	FGF5	GNA11	MCL1	MYD88	PIK3R1	SLX4	
ATR	CDH1	ERBB3	FGF6	GNAQ	MDM2	NBN	PMS2	SMAD4	
BAP1	CDK12	ERBB4	FGF7	GNAS	MDM4	NF1	PPP2R2A	SMARCB1	
BARD1	CDK4	ERCC1	FGF8	HNF1A	MET	NOTCH1	PTCH1	SMO	
BCL2	CDK6	ERCC2	FGF9	HRAS	MLH1	NOTCH2	PTEN	SRC	
BCL6	CDKN2A	ERG	FGF10	IDH1	MLLT3	NOTCH3	PTPN11	STK11	
BRAF	CEBPA	ESR1	FGF14	IDH2	MPL	NPM1	RAD51	TERT	
BRCA1	CHEK1	EZH2	FGF23	INPP4B	MRE11A	NRAS	RAD51B	TET2	
BRCA2	CHEK2	FAM175A	FGFR1	JAK2	MSH2	NRG1	RAD51C	TP53	
Amplifications (from DNA)									
AKT2	BRCA2	CHEK1	ERCC2	FGF5	JFGF14	FGFR4	MDM4	NRG1	RAF1
ALK	CCND1	CHEK2	ESR1	FGF6	FGF19	JAK2	MET	PDGFRA	RET
AR	CCND3	EGFR	FGF1	FGF7	FGF23	KIT	MYC	PDGFRB	RICTOR
ATM	CCNE1	ERBB2	FGF2	FGF8	FGFR1	KRAS	MYCL1	PIK3CA	RPS6KB1
BRAF	CDK4	ERBB3	FGF3	FGF9	FGFR2	LAMP1	MYCN	PIK3CB	TFRC
BRCA1	CDK6	ERCC1	FGF4	FGF10	FGFR3	MDM2	NRAS	PTEN	
Fusions and Splice Variants (from RNA)									
ABL1	BRAF	EML4	ETV4	FGFR4	KIF5B	MYC	NTRK2	PIK3CA	TMPRSS2
AKT3	BRCA1	ERBB2	ETV5	FLI1	KIT	NOTCH1	NTRK3	PPARG	
ALK	BRCA2	ERG	EWSR1	FLT1	KMT2A(MLL)	NOTCH2	PAX3	RAF1	
AR	CDK4	ESR1	FGFR1	FLT3	MET	NOTCH3	PAX7	RET	
AXL	CSF1R	ETS1	FGFR2	JAK2	MLLT3	NRG1	PDGFRA	ROS1	
BCL2	EGFR	ETV1	FGFR3	KDR	MSH2	NTRK1	PDGFRB	RPS6KB1	

Table 2: Details of cancer types and associated genes

Cancer type	Genes	Inheritance		Type of alterations covered in the panel				NCCN / ESMO / ASCO recommended	Clinical relevance			Matching FDA approved, Off label agents	Clinical trials (Completed / Ongoing)
		S	G	SNV	CNV	Fu	SP		Dia	Pro	Pre		
Bladder Cancer	ATM	✓	✓	✓	✓						✓		
	ERBB3	✓		✓	✓						✓	Afatinib (ERBB2 & EGFR inhibitor 2 nd generation)	
	ERCC2	✓		✓	✓						✓	Cisplatin (Clinical evidence)	
	FGFR2	✓		✓	✓	✓					✓	BGJ-398, AZD4575, JNJ-42756493, Debio1347	
	FGFR3	✓		✓	✓	✓					✓	BGJ-398, JNJ-42756493, AZD-4575, Debio1347 (Clinical evidence)	
	MTOR	✓		✓							✓	Everolimus	
	RB1	✓	✓	✓							✓	Cisplatin (Chemotherapy)	
	TSC1	✓		✓						✓	✓	✓	mTOR inhibitors NCT02053662
Breast Cancer	AKT1	✓		✓							✓	Buparlisib	NCT03337724, NCT03310541
	ATM		✓	✓	✓			NCCN	✓	✓			
	BRCA1		✓	✓	✓		✓	NCCN, ESMO	✓	✓			NCT01611727, NCT02670668, NCT00673335
	BRCA2		✓	✓	✓		✓	NCCN, ESMO	✓	✓			NCT01611727, NCT02670668, NCT00673335
	CDH1		✓	✓				NCCN	✓	✓			
	CHEK2		✓	✓	✓			NCCN	✓	✓			
	ERBB2	✓		✓	✓	✓		NCCN, ESMO	✓	✓	✓	Trastuzumab, Bevacizumab, Lapatinib, Neratinib	NCT03321981
	ESR1	✓		✓	✓	✓		NCCN, ESMO			✓	Tamoxifen or an aromatase inhibitor resistance	NCT02988986
	FGFR1	✓		✓	✓	✓					✓	Pazopanib	
	FGFR2	✓		✓	✓	✓					✓	pan-FGFR kinase inhibitors	
	FGFR2	✓		✓	✓	✓					✓	Dovitinib	
	MLH1		✓	✓				NCCN			✓	Pembrolizumab	
	MRE11A		✓	✓									
	MSH2		✓	✓		✓		NCCN			✓	Pembrolizumab	
	MSH6		✓	✓				NCCN			✓	Pembrolizumab	
	NBN		✓	✓				NCCN	✓	✓			
	NF1		✓	✓				NCCN	✓	✓			
	PALB2		✓	✓				NCCN	✓				
	PIK3CA	✓		✓	✓	✓	✓				✓	Everolimus, aromatase inhibitor exemestane	NCT01633060
	PMS2		✓	✓				NCCN			✓	Pembrolizumab	
	PTEN		✓	✓	✓			NCCN	✓	✓			
	RAD51C		✓	✓				NCCN, ESMO					
	STK11		✓	✓				NCCN	✓	✓			
	TP53		✓	✓				NCCN	✓	✓			
Colorectal cancer	AKT1	✓		✓							✓	Buparlisib	
	APC		✓	✓				NCCN, ESMO	✓				
	ATM		✓	✓					✓				
	BRAF	✓		✓	✓	✓	✓	NCCN, ASCO		✓	✓	Cetuximab and Panitumumab	NCT02928224
	CDH1		✓	✓					✓				

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Cancer type	Genes	Inheritance		Type of alterations covered in the panel				NCCN / ESMO / ASCO recommended	Clinical relevance			Matching FDA approved, Off label agents	Clinical trials (Completed / Ongoing)
		S	G	SNV	CNV	Fu	SP		Dia	Pro	Pre		
Colorectal cancer	CHEK2			✓					✓				
	EGFR	✓		✓	✓	✓		NCCN, ESMO, ASCO		✓		Bevacizumab	NCT00419159
	KRAS	✓		✓				NCCN, ASCO	✓	✓	✓	Cetuximab and Panitumumab	NCT00842257
	MLH1		✓	✓				NCCN, ESMO	✓		✓	Nivolumab, Pembrolizumab	NCT01876511
	MSH2		✓	✓		✓		NCCN, ESMO	✓		✓	Nivolumab, Pembrolizumab	NCT01876511
	MSH6		✓	✓				NCCN, ESMO	✓		✓	Nivolumab, Pembrolizumab	NCT01876511
	MUTYH		✓	✓				NCCN, ESMO	✓				
	NRAS	✓		✓				NCCN, ASCO	✓	✓	✓	Cetuximab and Panitumumab	NCT02296203
	PIK3CA	✓		✓	✓	✓		NCCN, ASCO			✓	Everolimus	
	PMS2		✓	✓				NCCN, ESMO	✓		✓	Nivolumab, Pembrolizumab	NCT01876511
	PTEN		✓	✓	✓			ASCO	✓				
	STK11		✓	✓					✓				
	TP53		✓	✓					✓				NCT03149679
GIST	APC		✓	✓						✓	✓	Response to Imatinib	PMC4872731
	ARID1A	✓		✓						✓	✓	Everolimus + Imatinib	NCT00510354
	ATR	✓		✓						✓	✓	PARP inhibitors: Olaparib, Rucaparib	
	BRAF	✓	✓	✓	✓	✓			✓	✓	✓	Vemurafenib	NCT01006980
	EGFR	✓		✓	✓	✓		ESMO	✓	✓	✓	Cetuximab	EudraCT:2007-004219-75
	FGFR1	✓		✓	✓	✓			✓	✓	✓	Pazopanib	NCT01323400
	FGFR2	✓		✓	✓	✓		ESMO	✓	✓	✓	BGJ398	NCT02257541
	HRAS	✓		✓					✓	✓		MEK inhibitors: Cobimetinib, Trametinib	NCT02342600
	KIT	✓		✓	✓		✓	NCCN, ESMO	✓	✓	✓	Sorafenib	NCT00116935
	KRAS	✓		✓								MEK inhibitors: Cobimetinib, Trametinib	
	MET	✓		✓		✓		ESMO	✓	✓	✓	Rilotumumab, ONA	NCT01697072
	MLH1	✓	✓	✓						✓	✓	Immunotherapy	NCT01876511
	MSH2	✓	✓	✓						✓	✓	Immunotherapy	NCT01876511
	MSH6	✓	✓	✓						✓	✓	Immunotherapy	NCT01876511
	NF1		✓	✓						✓	✓	Response to Imatinib, Selumetinib	NCT03109301
	NRAS	✓		✓	✓					✓	✓	MEK inhibitors: Cobimetinib, Trametinib	NCT02342600
	PDGFRA	✓		✓	✓	✓	✓	NCCN, ESMO	✓	✓	✓	Imatinib	
	PMS2	✓	✓	✓						✓	✓	Immunotherapy	NCT01876511
	STK11		✓	✓						✓	✓		
	SMAD4		✓	✓						✓	✓		
	TP53		✓	✓						✓	✓		NCT02171286
Glioma	ALK	✓	✓	✓	✓	✓		NCCN	✓		✓	Crizotinib (ALK inhibitor)	NCT00939770
	BRAF	✓		✓	✓	✓			✓	✓	✓	Dabrafenib and Selumetinib	NCT01089101
	CDKN2A	✓		✓							✓	CDK4/6 inhibitors	

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Cancer type	Genes	Inheritance		Type of alterations covered in the panel				NCCN / ESMO / ASCO recommended	Clinical relevance			Matching FDA approved, Off label agents	Clinical trials (Completed / Ongoing)
		S	G	SNV	CNV	Fu	SP		Dia	Pro	Pre		
Glioma	EGFR	✓	✓	✓	✓	✓		ESMO	✓	✓	✓	Rindopepimut	NCT01480479
	IDH1	✓		✓				ESMO	✓	✓			NCT03030066
	IDH2	✓		✓				ESMO	✓	✓			NCT02273739
	MET	✓		✓	✓	✓					✓	Crizotinib (ALK inhibitor)	
	NF1	✓	✓	✓				NCCN	✓		✓	Everolimus + Erlotinib, MEK & mTOR inhibitors, Bevacizumab	NCT00901849
	PDGFRA	✓		✓	✓	✓					✓	PDGFR inhibitors	
	TERT	✓		✓							✓	Eribulin (Macrocyclic aNA)	
Head and Neck Squamous Cell Carcinomas (HNSCC)	CDKN2A	✓		✓						✓			NCT02508246
	EGFR	✓		✓	✓	✓			✓		✓	Gefitinib	
	EP300	✓		✓						✓			
	FBXW7	✓		✓						✓			
	HRAS	✓		✓						✓			NCT02383927
	NOTCH1	✓		✓		✓				✓			
	NOTCH2	✓		✓		✓				✓			
	PIK3CA	✓		✓	✓	✓				✓			NCT02537223
Lung cancer	TP53	✓		✓						✓			NCT02508246
	AKT1	✓		✓								Buparlisib	
	ALK	✓		✓	✓	✓		NCCN, ESMO	✓		✓	Crizotinib, Ceritinib, Alectinib	NCT01772797
	BRAF	✓		✓	✓	✓		NCCN, ESMO	✓	✓	✓	Vemurafenib, Dabrafenib + trametinib	NCT02109653
	BRCA2		✓	✓	✓		✓				✓	PARP inhibitors	NCT01286987
	DDR2	✓		✓								Dasatinib + Erlotinib	
	EGFR	✓		✓	✓	✓		NCCN, ESMO	✓	✓	✓	Erlotinib, Gefitinib, Afatinib, and Osimertinib	NCT01415011, NCT02228369, NCT01967095
	ERBB2	✓		✓	✓	✓		NCCN, ESMO			✓	Afatinib, Neratinib	
	HRAS	✓		✓								Trametinib, Selumetinib	
	KRAS	✓		✓	✓			NCCN	✓	✓	✓	Trametinib, Selumetinib	
	MAP2K1	✓		✓								Trametinib, Selumetinib	
	MET	✓		✓			✓	NCCN, ESMO	✓	✓	✓	Crizotinib, Cabozantinib	NCT02864992
	NTRK1	✓				✓						TRKA/B/C inhibitor	
	NRAS	✓		✓	✓				✓	✓	✓	Trametinib, Selumetinib	
	PIK3CA	✓		✓	✓	✓						PI3K inhibitors	
	PTEN	✓		✓	✓							PI3K-AKT inhibitors	
Melanoma	RET	✓		✓	✓	✓		NCCN, ESMO	✓	✓	✓	Cabozantinib, Vandetanib, or Alectinib	NCT03131206
	RICTOR	✓			✓							TORC1/2 inhibitors	
	ROS1	✓		✓				NCCN, ESMO	✓	✓	✓	Crizotinib, Cabozantinib	NCT03399487
	BRAF	✓		✓	✓	✓		NCCN, ESMO	✓	✓	✓	MEK inhibitors, Trametinib, Vemurafenib, Dabrafenib+trametinib, Vemurafenib & Cobimetinib	NCT03088176, NCT01512251
	GNA11	✓		✓				ESMO	✓	✓	✓	PI3K pathway inhibitor + MEK inhibitors, Selumetinib, Vorinostat	
	GNAQ	✓		✓				ESMO	✓	✓	✓	HDAC inhibitors	NCT01587352

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Cancer type	Genes	Inheritance		Type of alterations covered in the panel				NCCN / ESMO / ASCO recommended	Clinical relevance			Matching FDA approved, Off label agents	Clinical trials (Completed / Ongoing)
		S	G	SNV	CNV	Fu	SP		Dia	Pro	Pre		
Melanoma	KIT	✓	✓	✓	✓		✓	NCCN, ESMO	✓	✓	✓	Imatinib, Sorafenib, Nilotinib, Sunitinib	NCT01099514, NCT02812693
	MAP2K1	✓		✓							✓	Cobimetinib, Trametinib	
	NRAS	✓		✓	✓			NCCN / ESMO	✓	✓	✓	Sorafenib, Tivantinib, BRAF inhibitors, MEK inhibitors, PDGFRA – PAN- inhibitor	NCT01781572, NCT01543113
Neuroblastoma	ALK	✓	✓	✓	✓	✓			✓		✓	Crizotinib	NCT02650401
	MYC	✓		✓	✓	✓					✓	FACT inhibitors	
	NF1	✓	✓	✓					✓	✓	✓	Retinoic Acids	
Ovarian cancer	AKT1	✓		✓							✓	AZD5363	
	ARID1A	✓		✓							✓	EZH2 inhibitors	NCT00861120
	ATR	✓		✓							✓	EZH2 inhibitors	NCT00861120
	BRAF	✓		✓	✓	✓		ESMO	✓	✓	✓	BRAF and MEK inhibitors	
	BRCA1		✓	✓	✓		✓	NCCN, ESMO	✓	✓	✓	PARP inhibitors	NCT02963688
	BRCA2		✓	✓	✓		✓	NCCN, ESMO	✓	✓	✓	PARP inhibitors (Olaparib)	NCT02963688
	ERBB2	✓		✓	✓	✓		ESMO	✓		✓	Trastuzumab (ERBB2 mAb inhibitor)	NCT00228358, NCT00003002
	KRAS	✓		✓	✓			ESMO	✓		✓	Decitabine + BCL2 inhibitor	NCT01149434
	PTEN	✓	✓	✓	✓			ESMO	✓		✓	PI3K / AKT, FRAP / MTOR, MEK inhibitors	NCT02286687
	RAD51C		✓	✓					✓		✓	PARP inhibitors	
	TP53		✓	✓				ESMO	✓		✓	WEE1 inhibitors	NCT01357161
Pancreatic cancer	BRCA1	✓	✓	✓	✓		✓	NCCN, ESMO	✓	✓	✓	PARP inhibitors	NCT02478892, NCT02184195
	BRCA2	✓	✓	✓	✓		✓	NCCN, ESMO	✓	✓	✓	Platinum Agent (Chemotherapy)	NCT03140670
	CDKN2A	✓		✓					✓				NCT02508246
	EGFR	✓		✓	✓	✓			✓		✓	Gefitinib	
	EP300	✓		✓					✓				
	FBXW7	✓		✓					✓				
	HRAS	✓		✓					✓				NCT02383927
	KRAS	✓		✓	✓			NCCN, ESMO	✓	✓	✓	PI3K pathway inhibitor+MEK inhibitors, Gemcitabine + MEK inhibitor	NCT03040986
	MLH1	✓	✓	✓				NCCN / ESMO	✓	✓	✓	Platinum of PARP inhibitors	
	MSH2	✓	✓	✓		✓		NCCN / ESMO	✓	✓	✓	Platinum of PARP inhibitors	
	NOTCH1	✓		✓		✓			✓				
	NOTCH2	✓		✓		✓			✓				
	PALB2	✓	✓	✓				NCCN / ESMO	✓	✓	✓	PARP inhibitors, Mytomycin C, Platinum Agent	NCT01585805
	PIK3CA	✓		✓	✓	✓			✓				NCT02537223
	PTEN	✓	✓	✓	✓						✓	AKT inhibitors	
	STK11	✓	✓	✓				NCCN / ESMO	✓	✓	✓	Everolimus	NCT03140670, NCT02478892
	TP53	✓		✓					✓				NCT02508246

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Cancer type	Genes	Inheritance		Type of alterations covered in the panel				NCCN / ESMO / ASCO recommended	Clinical relevance			Matching FDA approved, Off label agents	Clinical trials (Completed / Ongoing)
		S	G	SNV	CNV	Fu	SP		Dia	Pro	Pre		
Prostate cancer	AR	✓	✓	✓	✓		✓	ESMO			✓	Abiraterone, Enzalutamide, Flutamide	NCT02601014
	ATM	✓		✓	✓			NCCN	✓	✓	✓	Olaparib	NCT03442556
	BRCA1	✓	✓	✓	✓		✓	NCCN	✓		✓	Olaparib (PARP inhibitor)	NCT02598895, NCT02203513
	BRCA2	✓	✓	✓	✓		✓	NCCN	✓		✓	Olaparib (PARP inhibitor)	NCT01682772, NCT02203513
	MYC	✓		✓	✓	✓					✓	PIM inhibitors	
	PALB2	✓	✓	✓				ESMO	✓	✓	✓	PARP inhibitors	NCT02952534
	PTEN	✓		✓	✓						✓	PI3K pathway inhibitor + AR antagonists, Everolimus	NCT02573636
	RAF1	✓			✓	✓					✓	Pan-RAF inhibitors	
	TMRSS2	✓				✓		NCCN	✓	✓	✓	PARP inhibitors	NCT02588404
Thymic carcinoma	KIT	✓	✓	✓	✓		✓	NCCN, ESMO	✓	✓	✓	Imatinib, Dasatinib, Sunitinib and Sorafenib	
Thyroid cancer	BRAF	✓		✓	✓	✓		NCCN, ESMO	✓	✓	✓	Sorafenib, Vemurafenib, Dabrafenib + Lapatinib	NCT01700699
	HRAS	✓		✓							✓	Selumetinib	
	KRAS	✓		✓	✓						✓	Selumetinib	
	NRAS	✓		✓	✓						✓	Selumetinib	
	PTEN	✓		✓	✓						✓	PI3K pathway inhibitors	
	RET	✓	✓	✓	✓	✓	✓	NCCN	✓	✓	✓	Vandetanib, Cabozantinib	NCT03131206

S = Somatic G = Germline SNV = Single-Nucleotide Variant CNV = Copy Number Variant Fu = Fusion SP = Splice Variant Dia = Diagnostic Pro = Prognostic Pre = Predictive

Notes

Notes

Prima by MedGenome offers a wide range of Oncology and Haematology genetic tests, these include:

Molecular Testing for Hematological Malignancies, Comprehensive Leukemia Panel

Hereditary Cancer Panel, BRCA1 and BRCA2 gene test, Thalassemia Mutation Test

OncoTrack, OncoSelect, OncoFocus (Liquid Biopsy Test)

Differential Diagnosis

Prognosis

Risk Assessment

Therapy Selection

Surveillance

Therapy Monitoring

IGHV Gene Mutation Testing for CLL, Comprehensive Leukemia Panel, BCR-ABL1 gene fusion analysis

Comprehensive Tumor Gene Panel, Somatic Mutation Panel, Comprehensive Leukemia Panel, Molecular Testing for Lung Cancer

NGS based IRMA, BCR- ABL1 gene fusion analysis

For more information

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