

Rapid Turnaround | Actionable Insights

Acumen 505 delivers rapid and actionable genomic insights for all patients with advanced cancer. Utilizing an FDA-cleared and CE-IVD marked comprehensive to ensure every patient has access to personalized treatment options.

Product Features

Trustworthy: FDA cleared, and CE-IVD marked with overall clinical pass rate of 92.9%

Fast: results generated in 4-5 days via streamlined 6-hour hands-on workflow and automated bioinformatics that enable quick high-throughput runs

Actionable: 500+ solid tumor-related genes, including all FDA-approved and professional guidelines biomarkers, with easy-to-interpret results

Accessible: Local, community-based testing with simple ordering and reporting.

Development and Validation

Pan-Solid Tumor: 35 solid tumor types across 9 organ systems

Robust: >7,300 analytical samples tested

Rigorous: 15,000 hours of sequencing time

Accurate: 13 orthogonal methods used for comparison, including PCR, IHC, FISH, RNA and DNA-based NGS approaches



Simplified Clinical Workflow

A streamlined workflow allows for faster, more cost-effective access to reliable, high-quality, comprehensive genomic profiling (CGP) insights.













PGDx elioTM tissue complete Kit

Library Preparation

Targeted Hybrid Capture

Next-Generation Sequencing

Automated Bioinformatics

Clinical Report

Local, Community-based NGS Testing

Acumen 505 delivers rapid genomic insights without specimens or data ever leaving our local community. Our IVD test automatically generates intuitive clinical reports that guide personalized treatment decisions.

Eliminate delayed results from sending out specimens Access rapid comprehensive tumor genomic insights Personalize treatment decisions with confidence Explore new treatment options and clinical trial availability



Overview of Performance across Genomic Alterations

Alteration	Positi <mark>ve</mark> Pr <mark>edic</mark> tive Value	Negative Predictive Value		
EGFR Exon 19 Deletion	100.0%	100.0%		
EGFR L858R	100.0%	100.0%		
BRAF V600	100.0%	95.7%		
Hotspot Sequence	93.4%	100.0%		
Mutations Amplification	93.0%	92.9%		
Translocation	95.0%	98.0%		
Microsatellite Instability	98.8%	99.3%		
Tumor Mutation Burden	Spearman	Tested Range (Muts/Mb)		
	Correlation 0.903	0.2 - 89.7		

Accuracy of sequence mutations, comprising single nucleotide variants and insertion-deletions, were compared to two distinct orthogonal NGS panels to assess concordance. Amplifications and translocations were compared to biomarker specific FISH assays and detection of microsatellite instability was compared to PCR for concordance. Tumor mutation burden was correlated to whole-exome sequencing derived mutation burden to assess accuracy.

Assay Specifications

Sample requirements	Tumor only, FFPE tissue
Tumor purity minimum	20%
Sample pass rate	92.9%
DNA input required	50 ng minimum; 100 ng recommended
Library prep hands-on time	6 hours (2-day workflow)
Cases per sequencing run	15 samples and 1 control
Regions analyzed	Coding regions of 505 genes; non-coding regions for translocations
Panel size	2.23 Mb total
Read length	2x150bp
Average total coverage	2,300x
Bioinformatics	Patented PARE, Digital Karyotyping, and VariantDx
Turnaround time	4-5 days

PGDx elio tissue complete is an FDA cleared and CE-IVD marked device for use in tumor profiling applications.



Market-leading Sensitivity Across Variant Types

SNVs & Indels

Variant	MAF Range
Hotspot SNVs	3.1% - 5.4%
Non-hotspot SNVs	<mark>6.3</mark> % - 17.8%
Indels at homopolymer context	13.7% - 17.5%
Indels at non-homopolymer context	6.1% - 10.9%

Amplifications, Translocations, & MSI

variant	
MSI-H	18.1%
ERBB2 amplifications	4.4%
ALK tran <mark>sl</mark> ocations	5.6%
NTRK2 tra <mark>ns</mark> locations	30%
NTRK3 translocations	11.5%
RET translocations	12.8%

Reportable Variants with Evidence of Clinical Significance

Central Nervous System (CNS)								
BRAF	V600E							
H3F3A	K28M G34R, G34V							
IDH1	R132							
IDH2	R140Q, R172							
	Thyroid							
BRAF	V600E							
RET	A883F, C634, M918T							
	Breast							
ERBB2	Amplification							
PIK3CA	C420R, E542K, E545A, Q546, H1047							
	Castria							
	Gastric							
ERBB2	Amplification							
	Ovarian							
BRCA1/2	Deleterious Mutations							
	Prostate							
BRCA1/2	Deleterious Mutations							

	Rectal
BRAF	V <mark>6</mark> 00E
KRAS	Exon 2, 3, and 4 Mutations
NRAS	Exon 2, 3, and 4 Mutations
	Melanoma
BRAF	V600
KIT	D816H, D816Y, V825A
Non-9	Small Cell Lung Cancer
	(NSCLC)
ALK	Translocations
BRAF	
	G719. S768I. T790M. L858R.
EGER	L861Q, Exon 19 Deletions,
	Exon 20 Insertions
ERBB2	V659E, Exon 20 Deletions,
KDAS	Exon 20 Insertions
MET	G12, G13
DET	Exon 14, Splice Site Events
	Iranslocations

Gastro-Intestinal Stromal Tumors (GISTs)								
BRAF	V600E							
KIT	V825A, Exon 9 Mutations, Exon 11 Mutations							
PDGFRA	V561D, D842V							
	Pancreatic							
BRCA1/2	2 Deleterious Mutations							
	Colon							
BRAF	V600E							
KRAS	Exon 2, 3, and 4 Mutations							
NRAS	Exon 2, 3, and 4 Mutations							
	Solid Tumor							
MSI	MSI-H/MSS							
ТМВ	Muts/Mb							
NTRK2	Translocations							

Translocations

NTRK3

Intended Use

The PGDx elio™ tissue complete assay is a qualitative in vitro diagnostic device that uses targeted next generation sequencing of DNA isolated from formalin-fixed, paraffin-embedded tumor tissue from patients with solid malignant neoplasms to detect tumor gene alterations in a broad multi-gene panel. PGDx elio tissue complete is intended to provide tumor mutation profiling information on somatic alterations (SNVs, small insertions and deletions, one amplification and four translocations), microsatellite instability (MSI) and tumor mutation burden (TMB) for use by qualified healthcare professionals in accordance with professional guidelines in oncology for previously diagnosed cancer patients and is not conclusive or prescriptive for labeled use of any specific therapeutic product.



Gene Panel

Proprietary method for MSI and TMB. Full coding and specific intron analyses in 505 well-characterized cancer genes.

ABL2 BMRPAI CIC ERB2 FOFE HNPIA KRAS MYCN PIX3C2B RAD51 SMAD3 TOP2A ABL2 BRAF CREHP ERB5 FOFE HRAD LATS1 MYCNB PIX3C3 RAD51 SMARCA TP53 ACVRIB BRCA2 CSF1 ERC1 FOFE HSP30A1 LMO1 PIX3C3 RAD51 SMARCD1 TRAF7 ALT1 BRIP1 CSF3 ERC2 FFH LCOSC3 FLN NCOR1 PIX3C5 RAD51 SMARCD1 TSAT ALT3 BTG2 CSF3 ERC26 FLC1 ID1 LZTR NF2 PIX3C3 RAD51 SOX10 TYR03 ALCX128 BUBIB CTL4 ERC66 FLT3 ID12 MAF NF212 PIX182 RAD51 SOX10 TYR03 ALCX128 BUBIB CTL4 ERC66 FLT3 ID12 MAF NF212 PIX1 SOX10 TYR03 ALCX18 BUBI	SNVs and Indels (505)											
AXIN2CDH1DIMPTSBFANCEGPC3JAK2MITPPAK7PAK7PAK7PAK1TERCTAPTAXLCDK12DOTILFANCFGPR124JAK3MKNK1PALB2PRKDCRYBPTERTYENTB2MCDK4E2F3FANCGGPR124JAK3MKNK1PALB2PRKDCRYBPTERTYENTBAP1CDK6EEDFANCIGRIN2AKAT6AMLH1PARP2PRSSSDHATET2ZNF217BARD1CDK8EGFL7FANCLGRM3KDM5AMPLPARP2PTCH1SDHAF2TGFBR1ZNF703BBC3CDKN1AEGFRFANCMGSK3BKDM5CMRE11APARP3PTENSDHATET2ZNF703BC121CDKN1EEIF1AXFASH3F3AKDM6AMSH2PAX5PTK2SDHCTIPARPBCL211CDKN2AEPAS1FBXW7H3F3CKEAP1MSH6PBRM1PTRDSETD2TLR4BCL211CDKN2AEPAS1FGF10HDAC1KELMS1RPDCD1PTROSF3B1TLR9BCL22CDKN2BEPCAMFGF10HDAC2KITMTAPPDCD1PTROSF3B1TLR9BCL211CDKN2CEPHA3FGF14HDAC6KLF4MTORPDCD1PTROSF3B1TLR9BCL22CDKN2BEPCAMFGF12HDAC2KITMTAPPDCD1L62PTRTSH201ATMEM127BCC6CC	SNVs an ABL1 ABL2 ACVR1 ACVR1 ACVR1B ADORA2A AKT1 AKT2 AKT3 ALK ALOX12B AMER1 APC AR ARAF ARAF ARAF ARID1A ARID1A ARID1B ARID2 ARID5B ASXL1 ASXL2 ATM ATR ATR AURKA AURKB AXIN1 AXIN1 AXIN1 AXIN1 AXIN1	BMPRIA BRAF BRCA1 BRCA2 BRD4 BRIP1 BTG1 BTG2 BTK BUB1B C110RF30 CALR CARD11 CASP8 CBFB CBL CCND1 CCND2 CCND3 CCNE1 CD22 CD274 CD276 CD79A CD79B CDC73 CD73 CD73	(505) CIC CREBBP CRKL CSF1 CSF1 CSF3 CSF3 CSF3 CTCF CTLA4 CTNNB1 CUL3 CUL4A CXCR2 CXCR4 CYLD CYP17A1 DAXX DCUN1D1 DDB2 DDR1 DDR2 DICER1 DIS3 DNMT1 DNMT3A DNMT3A	ERBB2 ERBB3 ERBB4 ERCC1 ERCC2 ERCC3 ERCC4 ERCC5 ERCC6 ERCC8 ERG ERRFI1 EST1 ETV1 ETV4 ETV5 ETV6 EWSR1 EXT1 EXT1 EXT2 EZH2 FAM175A FAM26 FANCA FANCB FANCC FANCD2 EANCC	FGF6 FGFR1 FGFR2 FGFR3 FGFR4 FH FLCN FLT1 FLT3 FLT4 FOXL2 FOXP1 FRS2 FUBP1 GABRA6 GATA1 GATA2 GATA3 GATA4 GATA6 GID4 GL11 GNA11 GNA13 GNAQ GNAS CDC7	HNF1A HRAS HSD3B1 HSP90AA1 HSP90AB1 ICOSLG ID3 IDH1 IDH2 IFNGR1 IGF1 IGF1R IGF2 IGF2R IKBKE IKZF1 IL10 IL7R INHBA INPP4A INPP4B INSR IRF2 IRF4 IRS1 IRS2 JAK1 IAI22	KRAS LATS1 LATS2 LMO1 LRP1B LTK LYN LZTR1 MAF MAGI2 MAML1 MAP2K2 MAP2K4 MAP2K4 MAP3K1 MAP3K13 MAP4K1 MAX MCL1 MDC1 MDM2 MDM4 MED12 MEF2B MEN1 MERTK MET	MYCN MYD88 MYOD1 NBN NCOA3 NCOR1 NF1 NF2 NFE2L2 NFKBIA NKX2-1 NKX3-1 NOTCH1 NOTCH1 NOTCH2 NOTCH4 NOTCH4 NPM1 NTCH3 NOTCH4 NPM1 NTCC2 NTRK1 NTRK2 NTRK1 NTRK3 NUP93 NUTM1 PAK3 PAK3 PAK3	PIK3C2B PIK3C3 PIK3C3 PIK3CA PIK3CD PIK3CD PIK3CD PIK3C2 PIK3R1 PIK3R2 PIK3R3 PIM1 PLCG2 PIK2 PMAIP1 PMS1 PMS2 PNRC1 POLD1 POLE POLH POLH POLH POLH POT1 PP2R2A PRP2R1A PPP2R2A PRDM1 PREX2 PRC4R1A PRC4	RAD51 RAD51B RAD51C RAD51C RAD51D RAD52 RAD54B RAD54L RAF1 RANBP2 RARA RASA1 RB1 RBM10 RECQL4 RE1 RET RFWD2 RHOA RICTOR RIT1 RNF43 ROS1 RPA1 RPS6KA4 RPS6KB2 RPTOR RUNX1	SMAD3 SMAD4 SMARCA4 SMARCD1 SMO SNCAIP SOCS1 SOX10 SOX17 SOX2 SOX9 SPEN SPOP SPTA1 SRC STAG2 STAT4 STK11 STK40 SUFU SUZ12 SYK TAF1 TBX3 TEK	TOP2A TP53 TP53BP1 TP63 TRAF7 TSC1 TSC2 TSHR TYRO3 U2AF1 VEGFA VHL VTCN1 WAS WEE1 WHSC1 WHSC111 WISP3 WRN WT1 XIAP XPA XPA XPC XPO1 XRCC1 XRCC2 XRCC3 YA D1
BARD1CDK8EGFL7FANCLGRM3KDM5AMPLPARP2PTCH1SDHAF2TGFBR1ZNF703BBC3CDKN1AEGFRFANCMGSK3BKDM5CMRE11APARP3PTENSDHBTGFBR2BCL2CDKN1BEIF1AXFASH3F3AKDM6AMSH2PAX5PTK2SDHCTIPARPBCL211CDKN1CEP300FAT1H3F3BKDRMSH3PAX8PTPN11SDHDTLR4BCL2L11CDKN2AEPAS1FBXW7H3F3CKEAP1MSH6PBRM1PTRDSETD2TLR7BCL2L2CDKN2BEPCAMFGF10HDAC1KELMSTIRPDCD1PTPR0SF3B1TLR8BCL2CDKN2CEPHA3FGF12HDAC2KITMTAPPDCD1LG2PTPR3SGK1TLR9BCC6CDKN2CEPHA3FGF14HDAC6KLF4MTORPDGFRAPTPRTSH2D1ATMEM127BCORL1CHD2EPHA3FGF19HGFKLHL6MUTYHPDGFRBQKISHQ1TMPRS2BCRCHD4EPHA7FGF23HIST1H1CKMT2AMYBPDK1RAC1SL12TNFAIP3BIRC2CHEK1EPHB1FGF3HIST1H2BDKMT2CMYCPDPK1RAD50SMAD2TOP1	ASXL2 ATM ATR ATRX AURKA AURKA AURKB AXIN1 AXIN2 AXL B2M BAP1	CD22 CD274 CD276 CD70 CD79A CD79B CDC73 CDH1 CDK12 CDK4 CDK6	DDB2 DDR1 DDR2 DICER1 DIS3 DNMT1 DNMT3A DNMT3B DOT1L E2F3 EED	EZH2 FAM175A FAM26C FANCA FANCB FANCC FANCC FANCC FANCE FANCF FANCG FANCI	GATA6 GID4 GLI1 GNA11 GNA13 GNAQ GNAS GPC3 GPR124 GREM1 GRIN2A	INPP4B INSR IRF2 IRF4 IRS1 IRS2 JAK1 JAK2 JAK3 JUN KAT6A	MDM2 MDM4 MED12 MEF2B MEN1 MERTK MET MITF MKNK1 MLH1 MLH3	NTRKI NTRK2 NTRK3 NUP93 NUTM1 PAK1 PAK3 PAK7 PALB2 PARK2 PARK2 PARP1	POT1 PPARG PPP2R1A PRDM1 PREX2 PRKAR1A PRKCI PRKDC PRSS1 PRSS8	RNF43 ROS1 RPA1 RPS6KA4 RPS6KB2 RPTOR RUNX11 RUNX111 RYBP SBDS SDHA	STK40 SUFU SUZ12 SYK TAF1 TBX3 TEK TERC TERT TET1 TET2	XIAP XPA XPC XPC1 XRCC1 XRCC2 XRCC3 YAP1 YES1 ZBTB2 ZNF217
	BARD1 BBC3 BCL2L1 BCL2L1 BCL2L2 BCL6 BCOR BCORL1 BCR BIRC2 BLM	CDK8 CDKN1A CDKN1B CDKN1C CDKN2A CDKN2B CDKN2C CEBPA CHD2 CHD4 CHEK1 CHEK1 CHEK2	EGFL7 EGFR EIF1AX EP300 EPAS1 EPHA2 EPHA3 EPHA5 EPHA7 EPHB1 EPHB4	FANCL FANCM FAS FAT1 FBXW7 FGF10 FGF12 FGF14 FGF19 FGF23 FGF3 FGF3 FGF4	GRM3 GSK3B H3F3A H3F3C HDAC1 HDAC2 HDAC6 HGF HIST1H1C HIST1H2BD HIST1H3B	KDM5A KDM5C KDR KEAP1 KEL KIT KLF4 KLF4 KLHL6 KMT2A KMT2C KMT2D	MPL MRE11A MSH2 MSH3 MSH6 MST1R MTAP MTOR MUTYH MYB MYC MYCL	PARP2 PARP3 PAX5 PAX8 PBRM1 PDCD1 PDCD1LG2 PDGFRA PDGFRB PDK1 PDPK1 PHOX2B	PTCH1 PTEN PTK2 PTPRD PTPRO PTPRS PTPRT QKI RAC1 RAD21 RAD50	SDHAF2 SDHB SDHC SDHD SETD2 SF3B1 SGK1 SH2D1A SH2D1A SHQ1 SLIT2 SLX4 SMAD2	TGFBR1 TGFBR2 TIPARP TLR4 TLR7 TLR8 TLR9 TMEM127 TMPRSS2 TNFAIP3 TNFRSF14 TOP1	ZNF703

Amplifications - in IVD Mode (1)	Amplifications - in RUO Mode (27)								
ERBB2	AXL	CCND1	CCNE1	EGFR	FGFR3	KIT	MLH1	MYCN	PIK3CA
	BRCA1	CCND2	CD274	FGFR1	FGFR4	MDM	MSH2	PALB2	PIK3CB
	BRCA2	CCND3	CDK4	FGFR2	KDR	2 MET	MYC	PDGFRA	PIK3R1

Translocations - in IVD Mode (4)		Transl	ocations	- in RUO	Mode (1	6)			
ALK	NTRK2	AXL	EGFR	ETV6	FGFR1	FGFR3	NTRK1	PDGFRB	ROS1
RET	NTRK3	BRAF	ETV4	EWSR1	FGFR2	MYC	PDGFRA	RAF1	TMPRSS2