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University Hospitals Birmingham
NHS Foundation Trust

Molecular Pathology

Queen Elizabeth Hospital – Birmingham

Test Repertoire & Turnaround Times

MPDS provides an integrated, holistic testing service, offering end-to-end processing for solid tumours. This includes all elements of tissue microtomy, tumour assessment, and test preparation, ensuring that tissue consumption and process duplication are minimised. All TaTs stated include specimen preparation and pre-analytical preparation. The service utilizes a broad range of technologies including real time PCR, sequencing technologies (NGS, pyrosequencing and Sanger Sequencing), FISH, and IHC to provide comprehensive solid tumour testing for both tissue and ctDNA samples.

A detailed list of tests, technologies and turnaround times can be found in the tables below. MPDS utilizes a core range of tests to deliver routine testing. However, alternative techniques may be employed to deliver testing when required.

The laboratory tests fall under several different accreditation statuses, accreditation is to ISO 15189:2012. Regardless of the accreditation status (UKAS/ non-UKAS accredited), all tests are verified or validated to the same high standard.

DEFINITIONS

Accreditation Status	Definition
Accredited	Tests that are on the laboratory's UKAS Scope
Submitted for ETS	Tests that are currently with UKAS for assessment as an extension to scope (ETS)
Awaiting ETS submission	Validated tests, with plans to add to the laboratory's scope of accreditation
Non-accredited to scope	Validated tests but currently not planned to be submitted for extension to scope
Ongoing service development	Testing is offered as part of an ongoing service development

RAPID TESTING SERVICE

MPDS can offer rapid testing for the following mutations using real-time PCR on the Idylla testing platform.
Please contact the laboratory if you require urgent testing.

Test	Turnaround Time	Status
BRAF (codon 600)	24 hours	Accredited
KRAS (codons 12,13,117,61,146)	24 hours	Awaiting ETS
NRAS (codons 12,13,59,61,117,146) **BRAF (codon 600)**	24 hours	Submitted for ETS
EGFR (Deletions in exon 19, G719Xaa, S768I, L858R, L861Q, T790M, Exon20 insertions)	24 hours	Non-Accredited
MSI (MSI loci ACVR2A, BTBD7, DIDO1, MRE11, RYR3, SEC31A, SULF2 by High Resolution Melt (HRM)	24 hours	Submitted for ETS
IDH1 (5 mutations in codon 132) and IDH2 (4 mutations in codon 140, and 6 mutations in codon 172)	24 hours	Awaiting ETS
ALK/ROS/RET gene fusions and MET exon 14 skipping mutations (GeneFusion NSCLC assay)	24 hours	Submitted for ETS

DNA Next Generation Sequencing (NGS)

Panel	Turnaround Time	Status
QIAseq Custom Solid Tumour Panel	>90% in 15 working days	Awaiting ETS

Gene Targets												
AKT1	ALK	BRCA1	BRCA2	BRAF	CTNNB1	EGFR	ESR1	FGFR1	FGFR2	FOXL2	GNAQ	GNA11	HER2
IDH1	IDH2	KIT	KRAS	MET	NRAS	PDGFRA	PIK3CA	POLE	RET	TERT	TP53		

Panel	Turnaround Time	Status
Archer VariantPlex Pan Solid Tumour Panel	Contact the laboratory	Awaiting ETS

Gene Targets													
ABL1	ACVR1	AKT1	AKT2	AKT3	ALK	APC	AR	ARID1A	ARID1B	ARID2	ATM	ATR	ATRX
AURKA	B2M	BAP1	BARD1	BCOR	BLM	BMPR1A	BRAF	BRCA1	BRCA2	BRIP1	CCND1	CCND2	CCND3
CCNE1	CDH1	CDK12	CDK4	CDK6	CDKN2A	CDKN2B	CHD1	CHEK1	CHEK2	CIC	CSF1R	DAXX	DDR2
DDX3X	DICER1	EGFR	EIF1AX	EP300	EPCAM	ERBB2	ERBB3	ERBB4	ERCC1	ERCC2	ESR1	EZH2	FANCA
FANCI	FANCL	FBXW7	FGF19	FGFR2	FGFR3	FGFR4	FH	FLCN	FLT1	FLT3	FLT4	FOXA1	FOXL2
FUBP1	GNA11	GNAQ	GNAS	H3F3A	H3F3B	HIST1H3B	HIST1H3C	HNF1A	HRAS	IDH1	IDH2	JAK1	JAK2
JAK3	KDM6A	KDR	KEAP1	KIT	KLF4	KMT2C	KMT2D	KRAS	LZTR1	MAP2K1	MAP2K2	MAP3K1	MDM2
MDM4	MED12	MEN1	MET	MLH1	MPL	MRE11A	MSH2	MSH3	MSH6	MTOR	MUC16	MUTYH	MYC
MYCN	NBN	NF1	NF2	NKX2-1	NOTCH1	NOTCH2	NOTCH3	NOTCH4	NPM1	NRAS	NTRK1	NTRK2	NTRK3
PALB2	PBRM1	PDGFRA	PIK3CA	PIK3CB	PIK3R1	PLCB4	PMS2	POLD1	POLE	PPP2R1A	PPP2R2A	PRKD1	PTCH1
PTEN	PTPN11	RAD50	RAD51	RAD51B	RAD51C	RAD51D	RAD54L	RAF1	RB1	RET	RHOA	RICTOR	RNF43
ROS1	SDHA	SDHB	SDHC	SDHD	SETD2	SF3B1	SMAD2	SMAD4	SMARCA4	SMARCB1	SMO	SRC	SRSF2
STAG2	STK11	SUFU	TERT	TGFBR2	TP53	TP63	TRAF7	RSC1	TSC2	TSHR	U2AF1	VHL	XRCC2
XRCC3													

RNA Next Generation Sequencing (NGS)

Panel	Turnaround Time	Status
Archer FusionPlex® Lung	>90% in 15 working days	Submitted for ETS

Gene Targets													
ALK	BRAF	EGFR	FGFR1	FGFR2	FGFR3	KRAS	MET	NRG1	NTRK1	NTRK2	NTRK3	RET	ROS1

Panel	Turnaround Time	Status
Archer FusionPlex® Sarcoma v2	>90% in 15 working days	Submitted for ETS

Gene Targets													
ALK	BCOR	BRAF	CAMTA1	CCNB3	CIC	CSF1	CTNNB1	EGFR	EPC1	ERG	ESR1	ETV1	ETV4
ETV5	ETV6	EWSR1	FGFR1	FGFR2	FGFR3	FOS	FOSB	FOXO1	FUS	GLI1	HMGA2	JAZF1	MBTD1
MDM2	MEAF6	MET	MGEA5	MKL2	MYOD1	NCOA1	NCOA2	NCOA3	NR4A3	NTRK1	NTRK2	NTRK3	NUTM1
PAX3	PDGFB	PDGFRA	PHF1	PLAG1	PRKCA	PRKCB	PRKCD	RAF1	RET	ROS1	SS18	STAT6	TAF15
TCF12	TFE3	TFG	USP6	VGLL2	YAP1	YWHAE							

Targeted tests : qPCR and Pyrosequencing

Gene	Test	Mutation/Alteration Spectrum	Turnaround	Status
BRAF	COBAS BRAF/NRAS Mutation	G466/G469 V600E/D/K/R K601E	>90% in 5-7 working days	Accredited
	COBAS 4800 V600 Mutation	V600E	>90% in 5-7 working days	Accredited
KRAS	COBAS KRAS Mutation	Codons 12,13,59,61,117,146	>90% in 5-7 working days	Accredited
	Pyrosequencing	Codons 12,13,59,61,117,146	>90% in 7-10 working days	Accredited
NRAS	COBAS BRAF/NRAS Mutation	Codons 12,13,18,59,61,117,146	>90% in 5-7 working days	Accredited
	Pyrosequencing	Codons 12,13,61	>90% in 7-10 working days	Accredited
EGFR (tissue and ctDNA)	COBAS EGFR Mutation V2	Deletions in exon 19, G719Xaa, S7681, L858R, L861Q, T790M, Exon20 insertions	>90% in 5-7 working days	Accredited
	This test is accredited for use on solid tumour (FFPE) DNA and circulating tumour DNA from plasma.			
PIK3CA	COBAS PIK3CA Mutation	Codons 88,345,450,542,545,546,1043,1047,1049	>90% in 5-7 working days	Accredited
IDH1/IDH2	Therascreen IDH1/2 RGQ	IDH1 codons 100,132 IDH2 codon 172	>90% in 7-10 working days	Accredited
ESR1 (tissue and ctDNA)	APIS ESR1 mutation kit	E380Q, S463P, P535H, L536R, L536Q, L536H, L536P, Y537S, Y537N, Y537C and D538G	>90% in 5-7 working days	Awaiting ETS
	This test is validated for use on solid tumour (FFPE) DNA and circulating tumour DNA from plasma.			
MGMT	Therascreen MGMT Methylation Pyrosequencing	Methylation status of MGMT promoter	>90% in 7-10 working days	Accredited
MLH-1	Methylation Pyrosequencing	Methylation status of MLH-1 promoter	>90% in 7-10 working days	Accredited
HER-2 Mutation	AmoyDx HER-2 Mutation	13 mutations in the HER-2/ERBB2 gene	Contact the laboratory	Awaiting ETS
NTRK 1,2,3	AmoyDX NTRK Gene Fusion Detection Kit	109 fusions in NTRK 1,2, and 3 genes	Contact the laboratory	Submitted for ETS

Immunohistochemistry (IHC)

Gene	Test	Expression/Alteration Spectrum	Turnaround	Status
ALK	D5F3 on Ventana Benchmark Ultra	ALK Overexpression	>90% in 5-7 working days	Accredited
ROS-1	D4D6 on Ventana Benchmark Ultra	ROS-1 Overexpression	>90% in 5-7 working days	Accredited
PD-L1	Agilent 22C3 on Dako Autostainer Link 48	PD-L1 Expression	>90% in 5-7 working days	Accredited
	Agilent 28-8 on Dako Autostainer Link 48	PD-L1 Expression	>90% in 5-7 working days	Accredited
	Roche SP-142 on Ventana Benchmark Ultra	PD-L1 Expression	>90% in 5-7 working days	Accredited
	Roche SP-263 on Ventana Benchmark Ultra	PD-L1 Expression	>90% in 5-7 working days	Awaiting ETS
HER-2	VENTANA anti-HER-2/neu (4B5) Ventana Benchmark Ultra	HER-2 Overexpression	>90% in 5-7 working days	Accredited
NTRK	Pan-TRK on Ventana Benchmark Ultra	TRK A, B & C Overexpression	>90% in 5-7 working days	Submitted for ETS
MMR	Provided by the QEHB Cellular Pathology Department, under terms of MOU for service provision.			
BRAF	BRAF V600E (VE1) on Ventana Benchmark Ultra	BRAF V600E Mutant Isoform Expression	>90% in 5-7 working days	Awaiting ETS
SMARC	SMARCA4 on Ventana Benchmark Ultra	SMARCA4 Loss of expression	>90% in 5-7 working days	Non-Accredited
C-Met	SP44 on Ventana Benchmark Ultra	C-Met Overexpression	>90% in 5-7 working days	Non-Accredited
CLAUDIN 18.2	VENTANA CLDN18 (43-14A) IVD Assay on Ventana Benchmark Ultra	Claudin-18 Splice Variant 2 expression	>90% in 5-7 working days	Awaiting ETS

Fluorescence in situ hybridisation (FISH)

Gene	Test	Mutation Spectrum	Turnaround	Status
ALK	Vysis, LSI ALK Dual-Colour Break Apart Rearrangement Probe	Gene rearrangements involving the ALK gene region at 2p23	>90% in 15 working days	Accredited
ROS-1	ZytoLight SPEC ROS-1 Dual-Colour Break Apart Probe	Gene rearrangements involving the ROS-1 gene region at 6q22.1	>90% in 15 working days	Accredited
MET	ZytoLight Dual-Colour, SPEC MET Probe	Amplification of the MET gene region at 7q31.2	>90% in 15 working days	Non-Accredited
HER-2	Abbott PathVysion HER-2 Probe	Amplification of the HER-2 gene region at 17q12	>90% in 10 working days	Accredited
MDM2	Vysis MDM2/CEP 12 FISH Probe Kit	Amplification of the MDM2 gene region at 12q15	>90% in 15 working days	Accredited
SS18	Vysis LSI SS18 (18q11) Break Apart Probe	Gene rearrangements involving the SS18 gene region at 18q11	>90% in 10 working days	Accredited
1P19Q	Vysis 1p36/1q25 and 19q13/19p13 FISH Probe Kit	Deletions involving 1p36 & 19q13	>90% in 10 working days	Accredited
COL1A1-PDGFB FISH	POSEIDON COL1A1/PDGFB) Dual-Colour, Single Fusion Probe	COL1A1/PDGFB, t(17;22)(q21;q13) gene fusion	>90% in 10 working days	Non-Accredited
EWSR1	Vysis LSI EWSR1 Break Apart Probe	Gene rearrangements involving the EWSR1 gene region at 22q12	>90% in 10 working days	Accredited
NTRK 1	Zytovision ZytoLight SPEC NTRK1 Dual-Colour Break Apart Probe	Gene rearrangements involving the NTRK1 gene region at 1q22-q23	>90% in 10 working days	Non-Accredited
NTRK 2	Zytovision ZytoLight SPEC NTRK2 Dual-Colour Break Apart Probe	Gene rearrangements involving the NTRK2 gene region at 9q21.32-q21.33	>90% in 10 working days	Non-Accredited
NTRK 3	Zytovision ZytoLight SPEC NTRK3 Dual-Colour Break Apart Probe	Gene rearrangements involving the NTRK2 gene region at 15q25.3-q26.1	>90% in 10 working days	Non-Accredited
FUS	ZytoLight SPEC FUS Dual-Colour Break Apart Probe	Gene rearrangements involving the FUS gene region at 16p.11.2	>90% in 10 working days	Accredited
TFE3	ZytoLight SPEC TFE3 Dual-Colour Break Apart Probe	Gene rearrangements involving the TFE3 gene region at Xp11.23	>90% in 10 working days	Accredited
DDIT3	ZytoLight SPEC DDIT3 Dual-Colour Break Apart Probe	Gene rearrangements involving the DDIT3 gene region at 12q13.3	>90% in 10 working days	Accredited

NR4A3	ZytoLight SPEC NR4A3 Dual-Colour Break Apart Probe	Gene rearrangements involving the NR4A3 gene region at 9q22.33-q31.1	>90% in 10 working days	Accredited
USP6	ZytoLight SPEC USP6 Dual-Colour Break Apart Probe	Gene rearrangements involving the USP6 gene region at 17p13.2	>90% in 10 working days	Accredited
WWTR1	ZytoLight SPEC WWTR1 Dual-Colour Break Apart Probe	Gene rearrangements involving the WWTR1 gene region at 3q25.1	>90% in 10 working days	Accredited
CDK4	ZytoLight SPEC CDK4/CEN 12 Dual-Colour Break Apart Probe	Gene rearrangements involving the CDK4 gene region at 12q13.3-q14.1	>90% in 10 working days	Accredited
MYC	ZytoLight SPEC MYC Dual-Colour Break Apart Probe	Gene rearrangements involving the MYC gene region at 8q24	>90% in 10 working days	Awaiting ETS
IGH/MYC	Agilent (DAKO) Dual colour, Dual fusion IGH/MYC probe	IGK/MYC t(8;14)(q24;q32) gene fusion	>90% in 10 working days	Non-Accredited
IGK/IGL/MYC	Cytocell Tri-colour, dual fusion IGK/IGL/MYC probe	IGK/MYC t(2;8)(p11;q24) gene fusion and IGL/MYC t(8;22)(q24;11) gene fusion	>90% in 10 working days	Non-Accredited
BCL2	Vysis LSI BCL-2 Dual-Colour, Break Apart Probe	Gene rearrangements involving the BCL2 gene region at 18q21	>90% in 10 working days	Awaiting ETS
BCL6	Vysis LSI BCL-6 Dual-Colour, Break Apart Probe	Gene rearrangements involving the BCL6 gene region at 3q27	>90% in 10 working days	Awaiting ETS
IRF4/ DUSP22	ZytoLight SPEC IRF4,DUSP22 Dual-Colour Break Apart Probe	Gene rearrangements involving the IRF4,DUSP22 gene region at 6p25.3	>90% in 10 working days	Awaiting ETS
TP63	Empire Genomics TP63 Dual Colour, Breakapart probe	Gene rearrangements involving the TP63 gene at 3q28	>90% in 10 working days	Non-Accredited
MALT1	Vysis MALT1 Dual Colour, Breakapart probe	Gene rearrangements involving the MALT1 gene region at 18q21.3	>90% in 15 working days	Awaiting ETS
CCND1	Vysis CCND1 Dual Colour, Breakapart probe	Gene rearrangements involving the CCND1 gene region at 11q13	>90% in 15 working days	Awaiting ETS
IGH	Vysis IGH Dual Colour, Breakapart probe	Gene rearrangements involving the IGH gene region at 14q32	>90% in 15 working days	Awaiting ETS
CIC	ZytoLight SPEC NR4A3 Dual-Colour Break Apart Probe	Gene rearrangements involving the CIC gene region at 19q13.2. A	>90% in 10 working days	Accredited
FOXO1	ZytoLight SPEC NR4A3 Dual-Colour Break Apart Probe	Gene rearrangements involving the FOXO1 gene region at 13q14	>90% in 10 working days	Accredited

FGFR2	ZytoLight SPEC FGFR2 Dual-Colour Break Apart Probe	Gene rearrangements involving the FGFR2 gene region at 10q26.13	>90% in 10 working days	Non-Accredited
CDKN2A/B	Vysis LSI CDKN2A/B Dual Colour, Break Apart Probe	Deletions involving the CDKN2A/B (p16) gene region at 9p21	>90% in 10 working days	Non-Accredited
MAML2	Zytolight MAML2 dual colour, breakapart probe	Geme rearrangements involving the MAML2 gene region at 11q21	>90% in 10 working days	Ongoing service development
MYB	Zytolight MYB dual colour, breakapart probe	Gene rearrangements involving the MYB gene region at 6q23.2-q23.3	>90% in 10 working days	Ongoing service development

In situ hybridisation (ISH)

Gene	Test	Mutation Spectrum	Turnaround	Status
EBER	Ventana Inform EBER Probe	Expression of Epstein Barr virus encoded RNA	Contact the laboratory	Non-Accredited
HPV	Zytovision HPV Genotyping Kit	PCR array detecting 41 clinically relevant high and low risk genotypes	Contact the laboratory	Non-Accredited

Identity Testing

Gene	Test	Mutation Spectrum	Turnaround	Status
Multiplex-STR	Promega Gene Print 24 System	22 autosomal loci, 2 sec-specific loci	>90% in 15 working days	Non-Accredited