

Molecular Pathology

Queen Elizabeth Hospital – Birmingham

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), FISH₁ 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 15189:2022. 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

Test Repertoire & Turnaround Times

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

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 FusionPlex® Lung									>90% in 15 working days			Accredited	
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			Accredited	
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	Accredited

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	Accredited
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	Non-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	Non-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	Accredited
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	Accredited
BCL6	Vysis LSI BCL-6 Dual-Colour, Break Apart Probe	Gene rearrangements involving the BCL6 gene region at 3q27	>90% in 10 working days	Accredited
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	Accredited
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	Accredited
CCND1	Vysis CCND1 Dual Colour, Breakapart probe	Gene rearrangements involving the CCND1 gene region at 11q13	>90% in 15 working days	Accredited
IGH	Vysis IGH Dual Colour, Breakapart probe	Gene rearrangements involving the IGH gene region at 14q32	>90% in 15 working days	Accredited
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	Gene 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 sex-specific loci	>90% in 15 working days	Non-Accredited