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Test Repertoire & TAT's 2021

MPDS utilizes a broad range of technologies including real time PCR, sequencing technologies (SANGER sequencing, pyrosequencing and NGS), FISH and IHC to provide comprehensive solid tumour testing. 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's tests fall under a number of different accreditation statuses. Regardless of accreditation status all tests are verified or validated to the same high standard regardless if they are to be part or outside the UKAS accredited test scope.

Accreditation Status	Definition
Accredited	Tests that are on the laboratory's UKAS Scope
Submitted for ETS scope	Tests that are currently with UKAS for assessment as an extension to scope
Awaiting ETS accreditation	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

Please note: the laboratory is able to offer rapid testing for the following mutations using real-time PCR on the Idylla testing platform. Please contact the laboratory if urgent testing is required.

Test	Turnaround Time	Accreditation Status
BRAF (codon 600)	24 hours	Accredited
KRAS (codons 12,13,117,61,146)	24 hours	Awaiting ETS
NRAS (codons 12,13,61) BRAF (codon 600)	24 hours	Awaiting ETS

TARGETED TESTS

Gene	Test	Mutation Spectrum	Turnaround Time	Accreditation Status
BRAF	COBAS BRAF/NRAS Mutation Test	G466/G469 V600E/D/K/R K601E	>90% in 5-7 days	Accredited
	COBAS 4800 V600 Mutation Test	V600E	>90% in 5-7 days	Accredited
	IDYLLA BRAF Mutation Test	V600E/D/K/R/M	See rapid testing table	Accredited
KRAS	COBAS KRAS Mutation Test	Codons 12,13,59,61,117,146	>90% in 5-7 days	Accredited
	Pyrosequencing	Codons 12,13,59,61,117,146	>90% in 7-10 days	Accredited
	IDYLLA KRAS Mutation Test	Codons 12,13,59,61,117,146	48hrs for urgent referrals	Awaiting ETS
NRAS	COBAS BRAF/NRAS Mutation Test	Codons 12,13,18,59,61,117,146	>90% in 5-7 days	Accredited
	Pyrosequencing	Codons 12,13,61	>90% in 7-10 days	Accredited
	IDYLLA NRAS/BRAF Mutation Test	Codons 12,13,18,59,61,117,146	See rapid testing table	Awaiting ETS
EGFR	COBAS EGFR Mutation Test V2	Deletions in exon 19, G719Xaa, S7681, L858R, L861Q, T790M, (3) Exon20 insertions	>90% in 5-7 days	Accredited
	This test is accredited for use on solid tumour DNA and circulating tumour DNA from plasma.			
EGFR	Therascreen EGFR	Deletions in exon 19, G719Xaa, S7681, L858R, L861Q, T790M, (3) Exon20 insertions	>90% in 5-7 days	Accredited
	IDYLLA EGFR Mutation Test	Deletions in exon 19, G719Xaa, S7681, L858R, L861Q, T790M, (3) Exon20 insertions	See rapid testing table	Non Accredited
PIK3CA	COBAS PIK3CA Mutation Test	Codons 88,345,450,542,545,546,1043,1047,1049	>90% in 5-7 days	Accredited
IDH1/IDH2	Therascreen IDH1/2 RGQ Test	IDH1 codons 100,132 IDH2 codon 172	Contact the laboratory	Accredited
MGMT Promoter Methylation	Therascreen MGMT Methylation Pyrosequencing	Methylation status of MGMT promoter	>90% in 7-10 days	Accredited
MLH-1 Promoter	Methylation Pyrosequencing	Methylation status of MLH-1 promoter	>90% in 7-10 days	Accredited
HER-2 Mutation	AmoyDx HER-2 Mutation Detection Test	13 mutations in the HER-2 gene	Contact the laboratory	Ongoing service development

MSI (Microsatellite Instability)	High Resolution Melt (IDYLLA)	MSI loci ACVR2A, BTBD7, DIDO1, MRE11, RYR3, SEC31A, SULF2	Contact the laboratory	Awaiting ETS
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SEQUENCING				
Gene	Test	Mutation Spectrum	Turnaround Time	Accreditation Status
KIT	Sanger Sequencing	Exons 8,9,11,13,17	>90% in 20 days	Accredited
PDGFRA	Sanger Sequencing	Exons 12,14,18	>90% in 20 days	Accredited
BRAF	Sanger Sequencing	Exons 15	>90% in 20 days	Accredited
CTNNB1	Sanger Sequencing	Exon 3	Contact the laboratory	Accredited
ACTIONABLE PANEL	Next Generation Sequencing (NGS)	Hotspot panel (KRAS, NRAS, IDH1, IDH2, BRAF, EGFR, KIT, PDGFRA)	Contact the laboratory	Accredited

IMMUNOHISTOCHEMISTRY				
Gene	Antibody	Mutation Mechanism	Turnaround Time	Accreditation Status
ALK	D5F3 on Ventana Benchmark Ultra	ALK Overexpression	>90% in 5-7 days	Accredited
ROS-1	D4D6 on Ventana Benchmark Ultra	ROS-1 Overexpression	>90% in 5-7 days	Accredited
PD-L1	Agilent 22c3 on Dako Autostain 48	PD-L1 Expression	>90% in 5-7 days	Accredited
	Agilent 28-8 on Dako Autostain 48	PD-L1 Expression	>90% in 5-7 days	Accredited
	Roche SP-142 on Ventana Benchmark Ultra	PD-L1 Expression	>90% in 5-7 days	Accredited

HER-2	VEN anti-HER-2/neu (4B5) Ventana Benchmark Ultra	HER-2 Overexpression	Contact the laboratory	Accredited
NTRK	Pan-TRK on Ventana Benchmark Ultra	TRK A, B & C Overexpression	Contact the laboratory	Awaiting ETS
Mismatch Repair (MMR)	Provided by the QEHB Cellular Pathology Department, under terms of MOU for service provision.			
HLA	Abcam HLA DR/DP/DQ on Dako Autostainer	[CR3/43] to HLA DR + DP + DQ Overexpression	Contact the laboratory	Awaiting ETS
BRAF	BRAF V600E (VE1) on Ventana Benchmark Ultra	BRAF V600E Mutant Isoform Expression	Contact the laboratory	Non-Accredited
SMARC	SMARCA4 on Dako Autostainer	SMARCA4 Loss of expression	Contact the laboratory	Non-Accredited

FISH TESTS

Gene	Probe	Spectrum	Turnaround Time	Accreditation Status
ALK	Vysis, LSI ALK Dual-Colour Break Apart Rearrangement Probe	Gene rearrangements involving the ALK gene region at 2p23	Contact the laboratory	Accredited
ROS-1	ZytoLight SPEC ROS-1 Dual-Colour Break Apart Probe	Gene rearrangements involving the ROS-1 gene region at 6q22.1	Contact the laboratory	Accredited
MET	ZytoLight Dual-Colour, SPEC MET Probe	Amplification of the MET gene region at 7q31.2	Contact the laboratory	Ongoing service development
HER-2	Abbott PathVysion HER-2 Probe	Amplification of the HER-2 gene region at 17q12	Contact the laboratory	Accredited
MDM2	Vysis MDM2/CEP 12 FISH Probe Kit	Amplification of the MDM2 gene region at 12q15	Contact the laboratory	Accredited
SS18	Vysis LSI SS18 (18q11) Break Apart Probe	Gene rearrangements involving the SS18 gene region at 18q11	Contact the laboratory	Accredited
1P19Q	Vysis 1p36/1q25 and 19q13/19p13 FISH Probe Kit	Deletions involving 1p36 & 19q13	Contact the laboratory	Accredited

COL1A1-PDGFB FISH	POSEIDON COL1A1/PDGFBt (17;22) Dual-Colour, Single Fusion Probe	COL1A1/PDGFB,t(17;22)(q21;q13) gene fusion	Contact the laboratory	Non Accredited
RET	ZytoLight SPEC RET Dual-Colour Break Apart Probe	Gene rearrangements involving the RET gene region at 10q11.21	Contact the laboratory	Non Accredited
NTRK 1	ZytoVision ZytoLight SPEC NTRK1 Dual-Colour Break Apart Probe	Gene rearrangements involving the NTRK1 gene region at 1q22-q23	Contact the laboratory	Ongoing service development
NTRK 2	ZytoVision ZytoLight SPEC NTRK2 Dual-Colour Break Apart Probe	Gene rearrangements involving the NTRK2 gene region at 9q21.32-q21.33	Contact the laboratory	Ongoing service development
NTRK 3	ZytoVision ZytoLight SPEC NTRK3 Dual-Colour Break Apart Probe	Gene rearrangements involving the NTRK2 gene region at 15q25.3-q26.1	Contact the laboratory	Ongoing service development
EWSR1	Vysis LSI EWSR1 Break Apart Probe	Gene rearrangements involving the EWSR1 gene region at 22q12	Contact the laboratory	Accredited
FUS	ZytoLight SPEC FUS Dual-Colour Break Apart Probe	Gene rearrangements involving the FUS gene region at 16p.11.2	Contact the laboratory	Accredited
TFE3	ZytoLight SPEC TFE3 Dual-Colour Break Apart Probe	Gene rearrangements involving the TFE3 gene region at Xp11.23	Contact the laboratory	Accredited
DDIT3	ZytoLight SPEC DDIT3 Dual-Colour Break Apart Probe	Gene rearrangements involving the DDIT3 gene region at 12q13.3	Contact the laboratory	Accredited
NR4A3	ZytoLight SPEC NR4A3 Dual-Colour Break Apart Probe	Gene rearrangements involving the NR4A3 gene region at 9q22.33-q31.1	Contact the laboratory	Accredited
USP6	ZytoLight SPEC USP6 Dual-Colour Break Apart Probe	Gene rearrangements involving the USP6 gene region at 17p13.2	Contact the laboratory	Accredited
WWTR1	ZytoLight SPEC WWTR1 Dual-Colour Break Apart Probe	Gene rearrangements involving the WWTR1 gene region at 3q25.1	Contact the laboratory	Accredited
CDK4	ZytoLight SPEC CDK4/CEN 12 Dual-Colour Break Apart Probe	Gene rearrangements involving the CDK4 gene region at 12q13.3-q14.1	Contact the laboratory	Accredited
MYC	ZytoLight Dual-Colour Break Apart Probe	Gene rearrangements involving the MYC gene region at 8q24	Contact the laboratory	Non Accredited

BCL-2	Vysis LSI BCL-2 Dual-Colour, Break Apart Probe	Gene rearrangements involving the BCL-2 gene region at 18q21	Contact the laboratory	Non Accredited
BCL-6	Vysis LSI BCL-6 Dual-Colour, Break Apart Probe	Gene rearrangements involving the BCL-6 gene region at 3q27	Contact the laboratory	Non Accredited
CIC	ZytoLight SPEC NR4A3 Dual-Colour Break Apart Probe	Gene rearrangements involving the CIC gene region at 19q13.2. A	Contact the laboratory	Accredited
FOXO1	ZytoLight SPEC NR4A3 Dual-Colour Break Apart Probe	Gene rearrangements involving the FOXO1 gene region at 13q14	Contact the laboratory	Accredited

ISH TESTS

Gene	Probe	Spectrum	Turnaround Time	Accreditation Status
EBER	Ventana Inform EBER Probe	Expression of EpsteinBarr encoded RNA	Contact the laboratory	Non-Accredited
HPV	Inform HPV III Family 16 Probe (8)	Probe cocktail demonstrating expression of the following genotypes 16, 18, 31, 33, 35, 45, 52, 56, 58, 66	Contact the laboratory	Non-Accredited

SOLID TUMOUR RNA MOLECULAR TESTS

Gene	Test	Mutation Spectrum	Turnaround Time	Accreditation Status
NTRK 1,2,3	AmoyDX NTRK Gene Fusion Detection Kit	109 Gene fusions in NTRK 1,2,3	Contact the laboratory	Ongoing service development
NTRK 1,2,3	Next Generation Sequencing (NGS) RNA SCAN NTRK	Gene fusions	Contact the laboratory	Ongoing service development

Expansion to include:

ALK, FGFR1, FGFR2, FGFR3, NTRK 1,2,3, ROS, RET & MET Exon 14 skipping	Next Generation Sequencing (NGS)	Gene fusions	Contact the laboratory	Accredited
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ctDNA TESTING SERVICE

Gene	Test	Mutation Spectrum	Turnaround Time	Accreditation Status
EGFR	COBAS EGFR Mutation Test V2	Deletions in exon 19, G719Xaa, S7681, L858R, L861Q, T790M, (3) Exon20 insertions	>90% in 3-5 days	Accredited

For further information, please contact the laboratory:

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