

## Test Repertoire & TAT's 2021

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	Validated but not accredited. Awaiting ETS
	COBAS 4800 V600 Mutation Test	V600E	>90% in 5-7 days	Accredited
	IDYLLA BRAF Mutation Test	V600E/D/K/R/M	48hrs for urgent referrals	Accredited
KRAS	COBAS KRAS Mutation Test	Codons 12,13,59,61,117,146	>90% in 5-7 days	Validated but not accredited. Awaiting ETS
	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	Non Accredited
NRAS	COBAS BRAF/NRAS Mutation Test	Codons 12,13,18,59,61,117,146	>90% in 5-7 days	Validated but not accredited. Awaiting ETS
	Pyrosequencing	Codons 12,13,61	>90% in 7-10 days	Accredited
	IDYLLA NRAS/BRAF Mutation Test	Codons 12,13,18,59,61,117,146	48hrs for urgent referrals	Non Accredited
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 us on solid tumour DNA and circulating tumour DNA from plasma			
	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	48hrs for urgent referrals	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	Samples tested as part of the ongoing service development

<b>MSI (Microsatellite Instability)</b>	<b>High Resolution Melt (IDYLLA)</b>	<b>MSI loci ACVR2A, BTBD7, DIDO1, MRE11, RYR3, SEC31A, SULF2</b>	<b>Contact the laboratory</b>	<b>Validated but not accredited. Awaiting ETS</b>
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<b>SEQUENCING</b>				
<b>Gene</b>	<b>Test</b>	<b>Mutation Spectrum</b>	<b>Turnaround Time</b>	<b>Accreditation Status</b>
<b>KIT</b>	<b>SANGER SEQUENCING</b>	<b>Exons 8,9,11,13,17</b>	<b>&gt;90% in 20 days</b>	<b>Accredited</b>
<b>PDGFRA</b>	<b>SANGER SEQUENCING</b>	<b>Exons 12,14,18</b>	<b>&gt;90% in 20 days</b>	<b>Accredited</b>
<b>CTNNB1</b>	<b>SANGER SEQUENCING</b>	<b>Exon 3</b>	<b>Contact the laboratory</b>	<b>Accredited</b>
<b>ACTIONABLE PANEL</b>	<b>NEXT GENERATION SEQUENCING (NGS)</b>	<b>Hotspot panel (KRAS, NRAS, IDH1, IDH2, BRAF, EGFR, KIT, PDGFRA)</b>	<b>Contact the laboratory</b>	<b>Accredited for use on solid tumour DNA but can also utilise circulating tumour DNA on ROU basis</b>

<b>IMMUNOHISTOCHEMISTRY</b>				
<b>Gene</b>	<b>Antibody</b>	<b>Mutation Mechanism</b>	<b>Turnaround Time</b>	<b>Accreditation Status</b>
<b>ALK</b>	<b>D5F3 on Ventana Benchmark Ultra</b>	<b>ALK Overexpression</b>	<b>&gt;90% in 5-7 days</b>	<b>Accredited</b>
<b>ROS-1</b>	<b>D4D6 on Ventana Benchmark Ultra</b>	<b>ROS-1 Overexpression</b>	<b>&gt;90% in 5-7 days</b>	<b>Accredited</b>
<b>PD-L1</b>	<b>Agilent 22c3 on Ventana</b>	<b>PD-L1 Overexpression</b>	<b>&gt;90% in 5-7 days</b>	<b>Accredited</b>
	<b>Agilent 28-8 on Dako Autostain 48</b>	<b>PD-L1 Overexpression</b>	<b>&gt;90% in 5-7 days</b>	<b>Accredited</b>
	<b>Roche SP-142 on Ventana Benchmark Ultra</b>	<b>PD-L1 Overexpression</b>	<b>&gt;90% in 5-7 days</b>	<b>Accredited</b>
<b>HER-2</b>	<b>VEN anti-HER-2/neu (4B5) Ventana Benchmark Ultra</b>	<b>HER-2 Overexpression</b>	<b>Contact the laboratory</b>	<b>Accredited</b>
<b>NTRK</b>	<b>Pan-TRK on Ventana Benchmark Ultra</b>	<b>TRK A, B &amp; C Overexpression</b>	<b>Contact the laboratory</b>	<b>Awaiting ETS</b>

<b>Mismatch Repair (MMR)</b>	Provided by the QEHB Pathology Department, under terms of MOU for service provision.			
<b>HLA</b>	Abcam HLA DR/DP/DQ on Dako Autostainer	[CR3/43] to HLA DR + DP + DQ Overexpression	Contact the laboratory	Awaiting ETS
<b>BRAF</b>	BRAF V600E (VE1) on Ventana Benchmark Ultra	BRAF Overexpression	Contact the laboratory	Not Accredited
<b>SMARC</b>	SMARCA4 on Dako Autostainer	SMARC Overexpression	Contact the laboratory	Not Accredited

<b>FISH TESTS</b>				
<b>Gene</b>	<b>Probe</b>	<b>Spectrum</b>	<b>Turnaround Time</b>	<b>Accreditation Status</b>
<b>ALK</b>	Vysis, LSI ALK dual colour break-apart rearrangement probe	Gene rearrangements involving the ALK gene region at 2p23	Contact the laboratory	Accredited
<b>ROS-1</b>	ZytoLight SPEC ROS-1 dual colour break-apart probe	Gene rearrangements involving the ROS-1 gene region at 6q22.1	Contact the laboratory	Accredited
<b>MET</b>	ZytoLight dual colour, SPEC MET probe	Amplification of the MET gene region at 7q31.2	Contact the laboratory	Samples tested as part of ongoing service development
<b>HER-2</b>	Abbott PathVysion HER-2 probe	Amplification of the HER-2 gene region at 17q12	Contact the laboratory	Accredited
<b>MDM2</b>	Vysis MDM2/CEP 12 FISH probe kit	Amplification of the MDM2 gene region at 12q15	Contact the laboratory	Accredited
<b>SS18</b>	Vysis LSI SS18 (18q11) break-apart probe	Gene rearrangements involving the SS18 gene region at 18q11	Contact the laboratory	
<b>1P19Q</b>	Vysis 1p36/1q25 and 19q13/19p13 FISH probe kit	Deletions involving 1p36 & 19q13	Contact the laboratory	Accredited
<b>COL1A1-PDGFB FISH</b>	POSEIDON COL1A1/PDGFBt (17;22) Dual-Colour, Single Fusion Probe	COL1A1/PDGFB,t(17;22)(q21;q13) gene fusion	Contact the laboratory	Non Accredited
<b>RET</b>	ZytoLight SPEC RET Dual-Colour Break Apart Probe	Gene rearrangements involving the RET gene region at 10q11.21	Contact the laboratory	Non Accredited

<b>NTRK 1</b>	Zytovision ZytoLight SPEC NTRK1 Dual-Colour break apart probe	Gene rearrangements involving the NTRK1 gene region at 1q22- q23	Contact the laboratory	Samples tested as part of ongoing service development
<b>NTRK 2</b>	Zytovision ZytoLight SPEC NTRK2 Dual-Colour break apart probe	Gene rearrangements involving the NTRK2 gene region at 9q21.32-q21.33	Contact the laboratory	Samples tested as part of ongoing service development
<b>NTRK 3</b>	Zytovision ZytoLight SPEC NTRK3 Dual-Colour break apart probe	Gene rearrangements involving the NTRK2 gene region at 15q25.3-q26.1	Contact the laboratory	Samples tested as part of ongoing service development
<b>EWSR1</b>	Vysis LSI EWSR1 break apart probe	Gene rearrangements involving the EWSR1 gene region at 22q12	Contact the laboratory	
<b>FUS</b>	ZytoLight SPEC FUS Dual-Colour break apart probe	Gene rearrangements involving the FUS gene region at 16p.11.2	Contact the laboratory	Validated but not accredited. Awaiting ETS.
<b>TFE3</b>	ZytoLight SPEC TFE3 Dual-Colour break apart probe	Gene rearrangements involving the TFE3 gene region at Xp11.23	Contact the laboratory	Validated but not accredited. Awaiting ETS.
<b>DDIT3</b>	ZytoLight SPEC DDIT3 Dual-Colour break apart probe	Gene rearrangements involving the DDIT3 gene region at 12q13.3	Contact the laboratory	Validated but not accredited. Awaiting ETS.
<b>NR4A3</b>	ZytoLight SPEC NR4A3 Dual-Colour break apart probe	Gene rearrangements involving the NR4A3 gene region at 9q22.33-q31.1	Contact the laboratory	Validated but not accredited. Awaiting ETS.
<b>USP6</b>	ZytoLight SPEC USP6 Dual-Colour break apart probe	Gene rearrangements involving the USP6 gene region at 17p13.2	Contact the laboratory	Validated but not accredited. Awaiting ETS.
<b>WWTR1</b>	ZytoLight SPEC WWTR1 Dual- Colour break apart probe	Gene rearrangements involving the WWTR1 gene region at 3q25.1	Contact the laboratory	Validated but not accredited. Awaiting ETS.
<b>CDK4</b>	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	Validated but not accredited. Awaiting ETS.
<b>MYC</b>	ZytoLight Dual- Colour break apart probe	Gene rearrangements involving the MYC gene region at 8q24	Contact the laboratory	Validated but not accredited. Awaiting ETS.
<b>BCL-2</b>	Vysis LSI BCL-2 Dual-Colou, break apart probe	Gene rearrangements involving the BCL-2 gene region at 18q21	Contact the laboratory	Validated but not accredited. Awaiting ETS.
<b>BCL-6</b>	Vysis LSI BCL-6 Dual-Colou, break apart probe	Gene rearrangements involving the BCL-6 gene region at 3q27	Contact the laboratory	Validated but not accredited. Awaiting ETS.

ISH TESTS				
Gene	Probe	Spectrum	Turnaround Time	Accreditation Status
EBER	Ventana Inform EBER probe	Expression of EpsteinBarr encoded RNA	Contact the laboratory	Not 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	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	Samples tested as part of ongoing service development
Translocation Panel	Next Generation Sequencing (NGS)	Gene fusions	Contact the laboratory	Samples tested as part of ongoing service development
Expansion to include:				
ALK, FGFR1, FGFR2, FGFR3, ROS, RET & MET Exon 14 skipping	Next Generation Sequencing (NGS)	Gene fusions	Contact the laboratory	Samples tested as part of ongoing service development

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.

RAPID TESTING SERVICE		
TEST	TAT FROM RECEIPT OF SPECIMEN	ASSAYS CURRENTLY INCLUDED IN OUR APPLICATION FOR ISO15189:2012 ACCREDITATION SCOPE
BRAF (codon 600)	24 HOURS	YES
KRAS (codons 12,13,117,61,146)	24 HOURS	VALIDATED BUT NOT ACCREDITED. AWAITING ETS
NRAS (codons 12,13,61) BRAF (codon 600)	COBAS BRAF/NRAS Mutation Test	VALIDATED BUT NOT ACCREDITED. AWAITING ETS