Schedule of Accreditation

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University Hospitals Birmingham NHS Foundation Trust

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Testing performed at the above address only

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS	Immunocytochemistry of Histopathology examinations to assist in detection of clinical abnormalities	
Slide-mounted FFPE sections	ALK Translocation	Automated IHC technique using Ventana Benchmark Platform; D5F3 clone (anti-ALK antibody); Manual interpretation of stained sections using microscopes SOP: MOL.S121
	HER2 Expression testing FOR Breast and Gastric Carcinoma	Automated IHC technique using Ventana Benchmark Platform; Ventana 4B5 assay (Roche); Manual interpretation of stained sections using microscopes. SOP: MOL.S121
	ROS1 Translocation	Automated IHC technique using Ventana Benchmark Platform; ROS1 (D4D6®) Rabbit mAb; Manual interpretation of stained sections using microscopes SOP: MOL.S121
	pan-TRK	Automated IHC using the Ventana Benchmark Ultra platform; pan-TRK rabbit monoclonal antibody Manual interpretation of stained sections using microscopes, SOP: MOL.S121

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS	Immunocytochemistry of Histopathology examinations to assist in detection of clinical abnormalities (cont'd)	
Slide-mounted FFPE sections (cont'd)	Detection of PD-L1 28-8 within melanoma cases	Dako autostain 48 link: Agilent pharmDx PD-L1 28-8 assay: SOP MOL.S112 Manual interpretation using light microscope MOL.S112
	Detection of PD-L1 SP142 within urothelial tumour cases	Automated IHC technique using Ventana BenchMark Ultra: Roche Ventana PD-L1 SP142 assay SOP MOL.S121 Manual interpretation using light microscope MOL.S121
	PDL-1 22C3Expression	Automated IHC technique using Dako autostain 48 link: PDL-1 22c3 (Dako) mAb (mouse); MOL.S112 Manual interpretation using light microscope. MOL.S112
	Molecular Pathology examination procedures for the purposes of clinical diagnosis	
Blood FFPE Tissue Fresh Tissue	Extraction of nucleic acids	Manual DNA extraction technique using QIAamp DNA FFPE Tissue kit (QIAGEN). SOP : MOL.S020 Plasma separation and Manual DNA extraction using the COBAS® cfDNA Sample Preparation Kit. SOP : MOL.S120
FFPE human tissue	RNA extraction from FFPE human tissue	Manual RNA extraction technique using QIAGEN RNeasy kit SOP: MOL.S086

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS: (cont'd)	Molecular Pathology examination procedures for the purposes of clinical diagnosis (cont'd)	
DNA extracted from primary samples	Quantification of nucleic acids	Fluorometric DNA quantification using Qubit analyser (Thermofisher). SOP : MOL.S043 DNA quantification using NanoDrop Lite (Thermofisher). Spectrophotometric quantification of DNA. SOP: MOL.S117
FFPE human tissue	Genefusion detection of known ALK, ROS, RET gene fusions and MET 14 exon skipping	Automated real time PCR using the Biocartis Idylla Diagnostic system, SOP: MOL.S128
FFPE human tissue	Microsatellite instability (MSI) biomarkers	Automated real time PCR using the Biocartis Idylla Diagnostic system, SOP: MOL.S128
FFPE human tissue	Molecular detection of abnormal sequences for cancer NRAS/BRAF mutation detection	Automated real time PCR using the Biocartis Idylla Diagnostic system, SOP: MOL.S128
DNA extracted from FFPE Tissue	BRAF (Codon 600)	Automated Idylla Real Time multiplex PCR; Biocartis Idylla Diagnostic system; Idylla™ BRAF Mutation Test). SOP: MOL.S128
DNA extracted from primary samples	Molecular detection of abnormal sequences for cancer	DNA Bisulphite Conversion. Manual technique with Thermal cycler PCR machines (Bioer GenePro (x2), Biorad C1000 Touch, Agilent Technologies SureCycler 8800 ; EpiTect Bisulfite Kits (QIAGEN) SOP : MOL.S144.

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS: (cont'd)	Molecular Pathology examination procedures for the purposes of clinical diagnosis (cont'd) Molecular detection of abnormal sequences for cancer (cont'd):	
Bisulphite Converted DNA	MGMT Promoter Region Methylation	Automated Real Time PCR using Thermal cycler PCR machines (Bioer GenePro (x2), Biorad C1000 Touch, Peqlab peqSTAR 2X, Labnet Multigene Optimax, Agilent Technologies SureCycler 8800; Pyrosequencer Q24. SOP: MOL.S037, SOP: MOL.S040
Bisulphite Converted DNA	MLH-1 Methylation	Automated Real Time PCR using Thermal cycler PCR machines (Bioer GenePro (x2), Biorad C1000 Touch, Peqlab peqSTAR 2X, Labnet Multigene Optimax, Agilent Technologies SureCycler 8800; Pyrosequencer Q24. SOP: MOL.S037, MOL.S040
DNA extracted from primary samples	KRAS (Codons 12+13; Codon 61; Codon 146) Mutation detection	Automated Real Time PCR using Thermal cycler PCR machines (Bioer GenePro (x2), Biorad C1000 Touch, Peqlab peqSTAR 2X, Labnet Multigene Optimax, Agilent Technologies SureCycler 8800; Pyrosequencer Q24. SOP: MOL.S037, SOP: MOL.S141
DNA extracted from primary samples	NRAS (Codons 12+13; Codon 61) Mutation	Automated Real Time PCR using Thermal cycler PCR machines (Bioer GenePro (x2), Biorad C1000 Touch, Peqlab peqSTAR 2X, Labnet Multigene Optimax, Agilent Technologies SureCycler 8800; Pyrosequencer Q24. SOP: MOL.S037, SOP MOL.S141
DNA extracted from primary samples	BRAF V600/NRAS/KRAS/EGFR mutation detection	Automated Myra Liquid based handling system for Cobas 4800 RT-PCR processes SOP: MOL.S078

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS: (cont'd)	Molecular Pathology examination procedures for the purposes of clinical diagnosis (cont'd): Molecular detection of abnormal sequences for cancer (cont'd):	
DNA extracted from primary samples	BRAF V600 Mutation detection	Automated Real Time PCR: Cobas 4800 using the Cobas 4800 BRAF V600 kit. SOP: PMP S015
DNA extracted from primary samples	BRAF/NRAS/EGFR/KRAS Mutation detection	Automated Real time PCR: Roche Cobas z480 analyser using the Roche BRAF/NRAS/EGFR Mutation Test kit or the Roche KRAS mutation test kit v2. SOP: PMP S078
DNA extracted from primary samples	EGFR (Exons 18-21) Mutation detection	Automated Real Time PCR: Cobas 4800 using the Cobas EGFR mutation kit. SOP: PMP S017.
DNA extracted from primary samples	PIK3CA (Exons 1+4+7+9+20) Mutation detection	Automated Real Time PCR: Cobas 4800 using the Cobas PIK3CA kit. SOP: PMP S030.
Extracted RNA from FFPE human tissue	Molecular detection of abnormal sequences for cancer, fusions detected within NTRK1, 2 and 3	Automated real time PCR using the AmoyDx NTRK gene fusion detection kit on the cobas Z480, set up using Cobas® 4800 system User Defined Workflow (UDF) on the Cobas z480 Analyser. SOP: MOL.S084
DNA extracted from primary samples	IDH1 /IDH2 (exons 4-5) Mutation detection	Automated Real Time PCR analysis of PCR products using Thermal cycler PCR machines (Bioer GenePro (x2), Biorad C1000 Touch, Peqlab peqSTAR 2X, Labnet Multigene Optimax, Agilent Technologies SureCycler 8800); RotorGeneQ; TherasceenIDH1/2 RGQ PCR kit SOP: MOL.S018, SOP MOL.S045

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS: (cont'd)	Molecular Pathology examination procedures for the purposes of clinical diagnosis (cont'd): Molecular detection of abnormal sequences for cancer (cont'd):	
DNA extracted from primary sample	Mutation detection of: KIT and PDGFRa CTNNB1	Manual technique using the Big Dye Direct sequencing kit (Life Sciences), Qiagen QIAspin, and the Applied Biosystems SeqStudio Genetic Analyzer SOP MOL.S031, MOL.S127
Extracted RNA from FFPE human tissue	Detection of genetic aberrations for the purpose of clinical diagnosis using Archer RNA NGS gene panels	Next Generation sequencing using Illumina MiSeq Archer NGS panels: ArcherDx FusionPlex Lung kit and ArcherDx Fusionplex Sarcoma v2 kit and analysis using Archer software 6.2 SOP: PMP_S084
	FISH examination procedures for the purposes of clinical diagnosis	
FFPE Tissue on a glass slide	HER2 Amplification for therapy stratification in breast and gastric cancer	Manual staining technique. Subjective interpretation of stained sections. SOP: MOL.S108, MOL.S147
	ALK Translocation	Manual staining technique. Subjective interpretation of stained sections. SOP: MOL.S108, MOL.S142
Paraffin embedded tissue	Detection of: Deletion at Chromosome 1 (1p36/1q25) and chromosome 19 (19q13/19p13)	Manual staining technique using Vysis commercial kits. Subjective interpretation of stained sections. SOP MOL.S108, MOL.S147
	Translocations and amplifications of MDM2 copy number at chromosome 12q15	SOP MOL.S147

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS (cont'd):	Molecular Pathology examination procedures for the purposes of clinical diagnosis (cont'd): FISH examination procedures for the purposes of clinical diagnosis	
Paraffin embedded tissue	Qualitative detection of translocations involving the human ROS1 gene at 6q22.1	Manual staining technique using Zytovision ROS1 dual colour break apart probe. Subjective interpretation of stained sections. SOP MOL.S108, MOL.S142
Paraffin embedded tissue	Detection chromosome anomalies, including rearrangements,amplifications and deletions	Manual staining technique using Zeiss Axio Imager Dako Hybridizer: MOL.S147 FISH Analysis and Data storage: MOL.S108 FISH Hybridization MOL.S138 Use of the Fluorescent Microscope and Image Capture System Using Breakapart probes: EWSR1 DDIT3 CIC FUS SS18 USP6 FOXO1 WWTR1 Amplification probes: MDM2

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS (cont'd):	Molecular Pathology examination procedures for the purposes of clinical diagnosis (cont'd):	
FFPE human tissue	FISH examination for the purpose of clinical diagnosis Detection of gene rearrangements associated with lymphoma and lymphoproliferative disorders'	Manual staining technique using the DAKO FISH kit manufacture instructions and in-house SOP. Using dual colour break-apart probes Zytolight MYC and DUSP22/IRF4, Vysis BCL2, BCL6, CCND1 and MALT1 SOP: MOL.S108 Analysis on fluorescence microscope, SOP: MOL.S142
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