Schedule of Accreditation

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8759

Accredited to ISO 15189:2012

University Hospitals Birmingham NHS Foundation Trust

Issue No: 007 **Issue date:** 20 October 2023

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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	
FFPE Tissue on a glass slide	ALK Translocation	Automated IHC technique using Ventana Benchmark Platform; D5F3 clone (anti-ALK antibody); Manual interpretation of stained sections using microscopes SOP: PMP_S035
	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: PMP_S035
	ROS1 Translocation	Automated IHC technique using Ventana Benchmark Platform; ROS1 (D4D6®) Rabbit mAb; Manual interpretation of stained sections using microscopes SOP: PMP_S035
	Detection of PD-L1 within melanoma cases	Dako autostain 48 link: Agilent pharmDx PD-L1 28-8 assay: SOP PMP_S068 Manual interpretation using light microscope PMP_S024

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)	
FFPE Tissue on a glass slide	Detection of PD-L1 within urothelial tumour cases	Automated IHC technique using Ventana BenchMark Ultra: Roche Ventana PD-L1 SP142 assay SOP PMP_S068 Manual interpretation using light microscope PMP_S024
	PDL-1 22C3 Translocation	Automated IHC technique using Dako autostain 48 link: PDL-1 22c3 (Dako) mAb (mouse); PMP_S068 Manual interpretation using light microscope. PMP_S024
	Molecular Pathology examination procedures for the purposes of clinical diagnosis	
Blood FFPE Tissue Fresh Tissue		Manual DNA extraction technique using COBAS® DNA sample preparation kit (ROCHE) ; QIAamp DNA FFPE Tissue kit (QIAGEN). SOP: PMP S014, PMP S020 Plasma separation and Manual DNA extraction using the COBAS® cfDNA Sample Preparation Kit. SOP: PMP S041

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	
DNA extracted from primary samples		Fluorometric DNA quantification using Qubit analyser (Thermofisher). SOP: PMP_S043 DNA quantification using NanoDrop Lite (Thermofisher). Spectrophotometric quantification of DNA. SOP: PMP_S025
DNA extracted from primary samples		DNA Bisulphite Conversion. Manual technique with Thermal cycler PCR machines (Bioer GenePro (x2), Biorad C1000 Touch, Peqlab peqSTAR 2X, Labnet Multigene Optimax, Agilent Technologies SureCycler 8800 ; EpiTect Bisulfite Kits (QIAGEN) SOP: PMP S032.
DNA extracted from FFPE Tissue	BRAF (Codon 600)	Automated Idylla Real Time multiplex PCR; Idylla Biocartis Diagnostic system; Idylla™ BRAF Mutation Test). SOP: PMP S058
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 Mutation detection KRAS mutation detection	Automated Real time PCR : Roche Cobas z480 analyser using the Roche BRAF/NRAS Mutation Test kit or the Roche KRAS mutation test kit v2. SOP: PMP 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	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.
DNA extracted from primary samples	EGFR (Exons 18-21) Mutation detection. 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; Therasceen EGFR RGQ PCR kit (QIAGEN) and IDH1/2 RGQ PCR kit SOP: PMP S018, SOP PMP S045
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: PMP S037, SOP: PMP S038
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: PMP S037, SOP PMP S038

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: PMP S037, SOP: PMP 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: PMP S037, PMP S040
DNA extracted from primary sample	Mutation detection of: KIT and PDGFRa CTNNB1 BRAF	Manual technique using the Big Dye Direct sequencing kit (Life Sciences), Qiagen QIAspin, and the Applied Biosystems SeqStudio Genetic Analyzer SOP PMP_S071
DNA extracted from primary samples	Mutation detection of sequence variants for the purpose of clinical diagnosis using gene panels: [KRAS exon 2, KRAS exon 3 (codons 38 to 83), KRAS exon 4 NRAS exon 2, NRAS exon 3 (codons 38 to 83), NRAS exon 4 BRAF exon 15 KIT exon 9 (codons 478-513), KIT exon 11, KIT exon 13, KIT exon 17 (codons 798-828) PDGFRA exon 12 and 18 EGFR exon 2 (codons 39-80), EGFR exon 18 to 24 IDH1 exon 4 (codons 95-138), IDH2 codon 172]	Next Generation Sequencing using Qiagen Actionable Panel. Library preparation using Qiagen GeneRead DNAseq Panel PCR reagent V2 chemistry. SOP: PMP S059 Illumina MiSeq next generation sequencing. SOP: PMP S060 Bioinformatics - Biomedical Genomics Workbench. SIO: PMP S061

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	
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: PMP_S036, PMP_S051
	ALK Translocation	Manual staining technique. Subjective interpretation of stained sections. SOP: PMP_S036, PMP_S052
Paraffin embedded tissue	Detection of: Deletion at Chromosome 1 (1p36/1q25) and chromosome 19 (19q13/19p13) Translocations and amplifications of MDM2 copy number at chromosome 12q15	Manual staining technique using Vysis commercial kits. Subjective interpretation of stained sections. SOP PMP_S036, PMP_051, PMP_S070
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 PMP_S036, PMP_S052

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		Manual staining technique using Zeiss Axio Imager Dako Hybridizer: PMP_S051; PMP_S052 and PMP_S070 FISH Analysis and Data storage: PMP_S081 FISH Hybridization PMP_S083 Use of the Fluorescent Microscope and Image Capture System
	Detection of human chromosome anomalies: Chromosome rearrangements /translocations Gene amplifications/deletions	Using Breakapart probes: EWSR1 DDIT3 CIC FUS NR4A3 SS18 USP6 TFE3 FOXO1 WWTR1 Amplification probes: MDM2 CDK4
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