


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

| | | |
|--|---|---|
|  <p>UKAS MEDICAL</p> <p>8759</p> <p>Accredited to ISO 15189:2012</p> | University Hospitals Birmingham NHS Foundation Trust | |
| | Issue No: 006 Issue date: 18 October 2021 | |
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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 | <u>Immunocytochemistry of Histopathology examinations to assist in detection of clinical abnormalities</u> | |
| 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 |



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| HUMAN BODY TISSUE AND FLUIDS | <u>Immunocytochemistry of Histopathology examinations to assist in detection of clinical abnormalities (cont'd)</u> | |
| 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 |
| | <u>Molecular Pathology examination procedures for the purposes of clinical diagnosis</u> | |
| 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 |



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| HUMAN BODY TISSUE AND FLUIDS: (cont'd) | <u>Molecular Pathology examination procedures for the purposes of clinical diagnosis</u> (cont'd) | |
| DNA extracted from primary samples | Molecular detection of abnormal sequences for cancer | Fluorometric DNA quantification using Qubit analyser (ThermoFisher). SOP: PMP_S043 |
| DNA extracted from primary samples | | DNA quantification using NanoDrop Lite (ThermoFisher). Spectrophotometric quantification of DNA. SOP: PMP_S025 |
| DNA extracted from FFPE Tissue | BRAF (Codon 600) | 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 primary samples | BRAF V600 Mutation detection | Automated Idylla Real Time multiplex PCR; Idylla Biocartis Diagnostic system; Idylla™ BRAF Mutation Test). SOP: PMP S058 |
| 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 |



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| HUMAN BODY TISSUE AND FLUIDS: (cont'd) | <u>Molecular Pathology examination procedures for the purposes of clinical diagnosis (cont'd):</u> | |
| DNA extracted from primary samples | Molecular detection of abnormal sequences for cancer (cont'd): 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 |



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| HUMAN BODY TISSUE AND FLUIDS: (cont'd) | <u>Molecular Pathology examination procedures for the purposes of clinical diagnosis (cont'd):</u> | |
| Bisulphite Converted DNA | Molecular detection of abnormal sequences for cancer (cont'd): 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 |



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| <p>HUMAN BODY TISSUE AND FLUIDS (cont'd):</p> <p>FFPE Tissue on a glass slide</p> <p>Paraffin embedded tissue</p> <p>Paraffin embedded tissue</p> | <p><u>Molecular Pathology examination procedures for the purposes of clinical diagnosis (cont'd):</u></p> <p><u>FISH examination procedures for the purposes of clinical diagnosis</u></p> <p>HER2 Amplification for therapy stratification in breast and gastric cancer</p> <p>ALK Translocation</p> <p>Detection of: Deletion at Chromosome 1 (1p36/1q25) and chromosome 19 (19q13/19p13)</p> <p>Translocations and amplifications of MDM2 copy number at chromosome 12q15</p> <p>Qualitative detection of translocations involving the human ROS1 gene at 6q22.1</p> | <p>Manual staining technique. Subjective interpretation of stained sections. SOP: PMP_S036, PMP_S051</p> <p>Manual staining technique. Subjective interpretation of stained sections. SOP: PMP_S036, PMP_S052</p> <p>Manual staining technique using Vysis commercial kits. Subjective interpretation of stained sections. SOP PMP_S036, PMP_051, PMP_S070</p> <p>Manual staining technique using Zytovision ROS1 dual colour break apart probe. Subjective interpretation of stained sections. SOP PMP_S036, PMP_S052</p> |



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| <p>HUMAN BODY TISSUE AND FLUIDS (cont'd):</p> <p>Paraffin embedded tissue</p> | <p><u>Molecular Pathology examination procedures for the purposes of clinical diagnosis (cont'd):</u></p> <p><u>FISH examination procedures for the purposes of clinical diagnosis</u></p> <p>Detection of human chromosome anomalies: Chromosome rearrangements /translocations Gene amplifications/deletions</p> | <p>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</p> <p>Using Breakapart probes: EWSR1 DDIT3 CIC FUS NR4A3 SS18 USP6 TFE3 FOXO1 WWTR1</p> <p>Amplification probes: MDM2 CDK4</p> |
| END | | |