Schedule of Accreditation

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University Hospital Southampton NHS Foundation Trust

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Testing performed by the Organisation at the locations specified below

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity	Location code
Address Molecular Pathology Duthie Link Building, Mailpoint 225 University Hospital Southampton NHS Foundation Trust Tremona Road Southampton Hampshire SO16 6YD **Local contact** Nicola Meakin	Molecular analysis of pathological specimens	MOLPATH

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUID AND TISSUE	Molecular Genetics examination activities for the purpose of clinical diagnosis	Examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
Various fresh sample types (DNA and RNA) Blood, bone marrow, other body fluids including but not limited to ascites, cerebrospinal fluid		Nucleic acid extraction DNA and RNA Automated extraction using Qiasymphony, QiaCube and Qiagen column extraction kits SOP MP1.14, MP1.15, MP1.16, MP1.19, MP1.22, MPG1.14,	MOLPATH
Various fresh sample types (DNA) Blood, bone marrow, other body fluids including but not limited to ascites, cerebrospinal fluid		Nucleic acid extraction Automated extraction using Qiagen EZ1 and EZ1 DNA extraction kits SOP MP1.3, MPG1.14,	MOLPATH
Fresh/Paraffin embedded tissue (DNA and RNA)		Nucleic acid extraction Manual extraction using Qiagen extraction columns SOP MP4.8, MP4.9, MP3.4, MP5.1, MP4.11, MP4.12, MPG4.9, MPG1.6	MOLPATH
Blood or bone marrow (RNA)	M-BCR-ABL1 quantification (p210, e13a2 and e14a2 subtypes) against ABL housekeeping gene to International Scale $MR^{4.5}$ (1/32,000)– 100%	Quantitative real time PCR using the Qiagen RotorGene 6000. RNA extraction with Qiagen kits and reverse transcription with Invitrogen MMLV. In house primers according to Europe Against Cancer programme recommendations, plus Qiagen fusion transcript standards SOP MP3.5, MP3.6	MOLPATH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUID AND TISSUE (cont'd)	Molecular Genetics examination activities (cont'd)	Documented in house methods and manufacturer's instructions	
Blood or bone marrow (RNA)	m-BCR-ABLquantification (p190, e1a2 subtype) against ABL housekeeping gene.	Quantitative real time PCR using the Qiagen RotorGene 6000. RNA extraction with Qiagen kits and reverse transcription with Invitrogen MMLV. In house primers according to Europe Against Cancer programme recommendations, plus Qiagen fusion transcript standards SOP MP3.5, MP3.7	MOLPATH
Blood or bone marrow (DNA). Other tissue can be tested.	Post stem cell transplant chimerism analysis and allele identification (D3S1358, THO1, D21S11, D18S51, PentaE, D5S818, D13S317, D7S820, D16S539, CSF1PO, PentaD, Amelogenin, vWA, D8S1179, TPOX, FGA) 0-100% (post-transplant chimerism analysis)	Semi-quantitative short tandem repeat analysis using PCR thermal cycler and capillary electrophoresis on Applied Biosystems 3500XL using Promega PowerPlex16. SOP MP3.12, MP5.4	MOLPATH
Blood or bone marrow (DNA). Other tissue can be tested.	JAK2 p.V617F mutation analysis ≥0.1-100%	Droplet digital PCR using the BioRad QX200 and BioRad PrimePCR ddPCR JAK2 V617F reagents SOP MP3.13	MOLPATH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUID AND TISSUE (cont'd)	Molecular Genetics examination activities (cont'd)	Documented in house methods and manufacturer's instructions	
Blood or bone marrow (DNA) or FFPE skin samples (DNA)	BRAF p.V600E mutation analysis ≥1-100%	Droplet digital PCR using the BioRad QX200 and BioRad PrimePCR ddPCR BRAF V600E reagents. SOP MP5.5	MOLPATH
Blood or bone marrow (DNA) or FFPE skin samples (DNA)	BRAF p.V600K mutation analysis ≥1-100%	Droplet digital PCR using the BioRad QX200 and BioRad PrimePCR ddPCR BRAF V600K reagents. SOP MP5.5	MOLPATH
Blood or bone marrow (DNA) or FFPE skin samples (DNA)	MYD88 p.L265P mutation analysis ≥0.1-100%	Droplet digital PCR using the BioRad QX200 and BioRad PrimePCR ddPCR MYD88 L265P reagents. SOP MP5.6	MOLPATH
Blood or extracted DNA	HLA-B*27 confirmatory genotyping	OptiGene Genie-HT using LAMP technology & LaCAR LAMP kits MP6.5	MOLPATH
Blood (DNA)	HLA-B57*01 SSP-PCR genotyping	SSP-PCR with Olerup HLA-B*57:01 kit using PCR thermal cycler and gel electrophoresis. SOP MP2.3	MOLPATH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUID AND TISSUE (cont'd)	Molecular Genetics examination activities (cont'd)	Documented in house methods and manufacturer's instructions	
Blood (DNA) and neuro tumour slides (DNA)	Methylation status of MGMT promoter by bisulphite modification and high-resolution melt analysis of 16 CpG sites. Positive or negative and estimation of DNA methylation quantification.	Qiagen EpiTect Plus FFPE Bisulphite kit, in house primers, and Qiagen EpiTect HRM PCR kit with high resolution melt using Qiagen RotorGene 6000. SOP MP4.12, MP4.13	MOLPATH
Various sample types (DNA)	T cell and B cell clonality studies	PCR with Invivoscribe BIOMED MasterMix kits, using PCR thermal cycler and capillary electrophoresis on Applied Biosystems 3500XL SOP MP4.1, MP4.2, MP4.3, MP4.4	MOLPATH
DNA extracted from Formalin Fixed paraffin-embedded tissue	MLH1 promoter hypermethylation testing	Qiagen Rotorgene using Rotorgene Real-time PCR and High resolution melt technology SOP MP4.14 and MP4.12	MOLPATH
Blood or extracted DNA	DPYD variant testing: DPYD*2D DPYD*13 rs67376798 rs56038477	OptiGene Genie-HT using LAMP technology & LaCAR LAMP kits MP6.2	MOLPATH
FFPE Tissue	Microsatellite instability testing	Applied Biosystems Genetic Analyser 3500, MP4.15	MOLPATH
DNA extracted from Formalin Fixed Paraffin-embedded tissue, Blood (EDTA), Fresh tissue.	IGHV mutation status analysis	Illumina MiSeq using Qiagen Next Generation Sequencing Panel SOP MP8.7	MOLPATH
Blood or extracted DNA	Factor II G20210A and Factor V LEIDEN polymorphisms	OptiGene Genie-HT using LAMP technology & LaCAR LAMP kits SOP MP6.3	MOLPATH
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