


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <b>9194</b>  Accredited to ISO 15189:2012	<b>University Hospital Southampton NHS Foundation Trust</b>	
	Issue No: 005 Issue date: 15 March 2020	
	<b>Molecular Pathology</b> Duthie Link Building, Mailpoint 225 University Hospital Southampton NHS Foundation Trust Tremona Road Southampton Hampshire SO16 6YD	<b>Contact: Rob Rowe</b> Tel: +44 (0) 2381206976 Fax: +44 (0)2381203871 E-Mail: Rob.Rowe@uhs.nhs.uk Website: www.uhspathology.co.uk

**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
<b>Address</b> Molecular Pathology Duthie Link Building, Mailpoint 225 University Hospital Southampton NHS Foundation Trust Tremona Road Southampton Hampshire SO16 6YD	<b>Local contact</b> Nicola Meakin	Molecular analysis of pathological specimens  MOLPATH



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
<b>HUMAN BODY FLUID AND TISSUE</b>	<u>Molecular Genetics examination activities for the purpose of clinical diagnosis</u>	Examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	MOLPATH
Various fresh sample types (DNA and RNA) Blood, bone marrow, other body fluids including but not limited to ascites, cerebrospinal fluid		<u>Nucleic acid extraction DNA and RNA</u> Automated extraction using Qiasymphony, QiaCube and Qiagen column extraction kits SOP MP1.14, MP1.15, MP1.16, MP1.19, MP1.22, MPG1.14,	
Various fresh sample types (DNA) Blood, bone marrow, other body fluids including but not limited to ascites, cerebrospinal fluid		<u>Nucleic acid extraction</u> Automated extraction using Qiagen EZ1 and EZ1 DNA extraction kits SOP MP1.3, MPG1.14,	
Fresh/Paraffin embedded tissue (DNA and RNA)		<u>Nucleic acid extraction</u> Manual extraction using Qiagen extraction columns SOP MP4.8, MP4.9, MP3.4, MP5.1, MP4.11, MP4.12, MPG4.9, MPG1.6	
Blood or bone marrow (RNA)	M-BCR-ABL quantification (p210, e13a2 and e14a2 subtypes) against ABL housekeeping gene to International Scale MR <sup>4.5</sup> (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



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HUMAN BODY FLUID AND TISSUE (cont'd)	<u>Molecular Genetics examination activities (cont'd)</u>	Documented in house methods and manufacturer's instructions	
Blood or bone marrow (RNA)	m-BCR-ABL quantification (p190, e1a2 subtype) against ABL housekeeping gene. MR <sup>4.5</sup> (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, MP3.7	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
Blood (DNA)	Factor V Leiden p.G1691A genotyping	SNP genotyping using Qiagen RotorGene 6000 by PrimerDesign FactorV genotyping kit. SOP MP3.1	MOLPATH
Blood (DNA)	Prothrombin p.G20210A genotyping	SNP genotyping using Qiagen RotorGene 6000 by PrimerDesign Prothrombin genotyping kit. SOP MP3.1	MOLPATH



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HUMAN BODY FLUID AND TISSUE (cont'd)	<u>Molecular Genetics examination activities (cont'd)</u>	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 (DNA)	Haemochromatosis HFE p.C282Y and p.H63D SSP-PCR genotyping	SSP-PCR with in house HFE primers for C282Y and H63D mutations using PCR thermal cycler and gel electrophoresis. SOP MP2.1	MOLPATH
Blood (DNA)	HLA-B*27 low resolution SSP-PCR molecular genotyping	SSP-PCR with Olerup SSP HLA-B*27 single well kit using PCR thermal cycler and gel electrophoresis. SOP MP2.2	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



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HUMAN BODY FLUID AND TISSUE (cont'd)	<u>Molecular Genetics examination activities (cont'd)</u>	Documented in house methods and manufacturer's instructions	
Blood (DNA)	HLA-DQA1 & DQB1 testing by SSP-PCR for disease association HLA-DQA1*02,05; DQB1*02,03:02 and HLA-DQB1*06:02, DQA1*01:02	SSP-PCR with Olerup HLA-DQA1*02,05; DQB1*02,03:02 and HLA-DQB1*06:02, DQA1*01:02 kits using PCR thermal cycler and gel electrophoresis. SOP MP2.6	MOLPATH
Blood (DNA) and FFPE tumour slides (DNA)	Loss of Heterozygosity 1p/19q by microsatellite analysis (D1S186, D1S199, D1S226, D1S2734, D19S112, D19S206, D19S219, D19S412)	Microsatellite PCR with in house primers using PCR thermal cycler and capillary electrophoresis on Applied Biosystems 3500XL. SOP MP4.11	MOLPATH
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
END			