


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>9597</p> <p>Accredited to ISO 15189:2012</p>	<p>Viapath Analytics LLP</p> <p>Issue No: 008 Issue date: 22 July 2021</p>	
	<p>The Laboratory for Molecular Haemato-Oncology Kings College Hospital</p> <p>The Rayne Institute 123 Coldharbour Lane London SE5 9RS</p>	<p>Contact: Tanya Scott</p> <p>Tel: +44 (0)20 7848 5835</p> <p>E-Mail: tanya.scott@nhs.net</p>
<p>Testing performed at the above address only</p>		

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>Fresh, frozen or fixed human tissue or cells (Blood and Bone marrow)</p> <p>Fresh, frozen or fixed human tissue or cells (Blood and Bone marrow)</p> <p>Fresh Peripheral Blood, Fresh Bone Marrow, Frozen Peripheral Blood, Frozen Bone Marrow, Specific Cell lineages extracted from fresh blood (CD3, 15, 19)</p> <p>Fresh cells (Blood and Bone marrow)</p> <p>RNA</p>	<p><u>Molecular Haemto-Oncology activities for the purpose of clinical diagnosis</u></p>	<p>Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:</p> <p>Genomic DNA extraction Blood DNA Purification System Maxwell 16 SOP LP-HAE-LMH004</p> <p>Genomic DNA extraction Manual Extraction (Qiagen) SOP LP-HAE-LMH009</p> <p>Automated Genomic DNA extraction - QIASymphony SP, Extraction kit validated: SP DNA Midi Kit. And SOP LP-HAE-LMH076</p> <p>RNA Extraction with Trizol SOP LP-HAE-LMH001</p> <p>cDNA preparation Reverse Transcriptase SOP LP-HAE-LMH005</p>
<p>cDNA synthesised in-house from the sample types listed above or received as primary sample type from an external source</p>	<p>BCR-ABL P210 Diagnosis and therapy monitoring</p>	<p>StepOnePlus real time PCR system SOP LP-HAE-LMH019</p>
<p>cDNA synthesised in-house from the sample types listed above or received as primary sample type from an external source</p>	<p>BCR-ABL P190 Diagnosis and therapy monitoring</p>	<p>StepOnePlus real time PCR system SOP LP-HAE-LMH025</p>



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	<u>Molecular Haemto-Oncology activities for the purpose of clinical diagnosis (cont'd)</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
cDNA synthesised in-house from the sample types listed above or received as primary sample type from an external source	PML-RARA AML-ETO INV16 Diagnosis and therapy monitoring	StepOnePlus real time PCR system SOP LP-HAE-LMH047
gDNA extracted in-house from the sample types listed above or received as primary sample type from an external source	JAK2 V617F Diagnosis	StepOnePlus real time PCR system SOP LP-HAE-LMH015
gDNA extracted in-house from the sample types listed above or received as primary sample type from an external source	BRAF V600E Diagnosis	StepOnePlus real time PCR system qualitative PCR using SOP LP-HAE-LMH069
gDNA extracted in-house from the sample types listed above or received as primary sample type from an external source	MYD88 L265P Diagnosis	StepOnePlus real time PCR system qualitative PCR using SOP LP-HAE-LMH072
gDNA extracted in-house from the sample types listed above or received as primary sample type from an external source	Chimerism monitoring including subset monitoring (CD3, CD15 & CD19)	Quantitative fragment analysis Applied Biosystems 3500XL Genetic analyser SOP LP-HAE-LMH018
gDNA extracted in-house from the sample types listed above or received as primary sample type from an external source	CALR Diagnosis	Non-quantitative fragment analysis Applied Biosystems 3500XL Genetic analyser SOP LP-HAE-LMH063
gDNA extracted in-house from the sample types listed above or received as primary sample type from an external source	JAK2 Exon 12 Diagnosis	Non-quantitative fragment analysis Applied Biosystems 3500XL Genetic analyser SOP LP-HAE-LMH056
gDNA extracted in-house from the sample types listed above or received as primary sample type from an external source	NPM1 Diagnosis	Non-quantitative fragment analysis Applied Biosystems 3500XL Genetic analyser SOP LP-HAE-LMH007



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	<u>Molecular Haemto-Oncology activities for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
gDNA extracted in-house from the sample types listed above or received as primary sample type from an external source	FLT3 ITD Diagnosis	Non-quantitative fragment analysis Applied Biosystems 3500XL Genetic analyser SOP LP-HAE-LMH007
gDNA extracted in-house from the sample types listed above or received as primary sample type from an external source	MPL Diagnosis	Allele-specific PCR Non-quantitative fragment analysis Gel electrophoresis SOP LP-HAE-LMH054
cDNA synthesised in-house from the sample types listed above or received as primary sample type from an external source. or gDNA extracted in-house from the sample types listed above or received as primary sample type from an external source	BCR-ABL Tyrosine Kinase RUNX1 TP53 SF3B1 Diagnosis	Next Generation Sequencing of PCR amplicons: Illumina Miseq-Next Generation Sequencer SOP LP-HAE-LMH067
Fresh, frozen or fixed human tissue or cells (Peripheral blood, Bone marrow, FFPE tissue blocks, FACS-sorted cells and Skin)	Myeloid Gene Panel Lymphoid Gene Panel	DNA Sequencing Using QiaSeq Targeted DNA Panels SOP LP-HAE-LMH083
gDNA extracted in-house from Peripheral blood, Bone marrow	Myeloproliferative Neoplasms JAK2 V617F JAK2 Exon 14 JAK2 Exon 12 CALR MPL	Custom Amplicon Sequencing using Illumina Adaptor and Indexing Methodology SOP LP-HAE-LMH081
Outputs from Next Generation Sequencer pipelines	Analysis of next generation sequencing	In-house developed pipeline Snappy with data displayed in the variant database SQVD. Variant scoring and sharing using VASA. SOPs LP-HAE-LMH077 and LP-HAE-LMH082



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<p>cDNA synthesised in-house from the sample types listed above or received as primary sample type from an external source</p> <p>gDNA extracted in-house from the sample types listed above or received as primary sample type from an external source.</p>	<p><u>Molecular Haemto-Oncology activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Detection of <i>BCR-ABL1</i> fusion transcripts e13a2, e13a3, e14a2, e14a3, e1a2, e1a3, e19a2, e19a3, e6a2, e6a3, e8a2, e8a3, e18a2 and e18a3</p> <p><u>Cytogenetics Haemto-Oncology activities for the purpose of clinical diagnosis</u></p> <p>SNP Array Karyotyping</p>	<p>Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:</p> <p>Multiplex PCR and Non-quantitative fragment analysis Applied Biosystems 3500XL Genetic analyser SOP LP-HAE-LMH0073</p> <p>ThermoFisher/ Affymetrix GeneChip® 3000 Scanner. Qualitative genotyping and intensity assessment allowing copy number and copy number neutral loss of heterozygosity detection using procedures: Affymetrix Single Nucleotide Polymorphism Karyotyping (LP-HAE-LMH074)</p> <p>LMH Authorisation and Results Reporting (LP-HAE-LMH059)</p>
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