

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 9597 Accredited to ISO 15189: 2022	Synnovis Analytics LLP	
	Issue No: 017	Issue date: 19 December 2025
	The Laboratory for Molecular Haemato-Oncology Kings College Hospital The Rayne Institute 123 Coldharbour Lane London SE5 9RS	Contact: Nura Ibrahim Tel: +44 (0) 20 3299 8367 E-Mail: nura.ibrahim@synnovis.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
The Laboratory for Molecular Haemato-Oncology Kings College Hospital The Rayne Institute 123 Coldharbour Lane London SE5 9RS	Local contact Nura Ibrahim (as above)	Molecular Haemato-Oncology Cytogenetic Haemato-Oncology	RI
Ground Floor, Hambledon Wing King's College Hospital Denmark Hill London SE5 9RS	Local contact Nura Ibrahim (as above)	Cytogenetics Immunophenotyping	HW



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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
<p>Fresh, frozen or fixed human tissue or cells (Blood and Bone marrow)</p> <p>Fresh and Frozen, Peripheral Blood and Bone Marrow, Specific Cell lineages extracted from fresh blood (CD3, 15, 19)</p> <p>Genomic DNA extracted in-house from the sample types listed above or received as primary sample type from an external source</p> <p>Fresh cells (Blood and Bone marrow)</p> <p>RNA extracted in-house from the sample types listed above or received as primary sample type from an external source</p> <p>cDNA synthesised 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></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 Manual Extraction (Qiagen) SOP PMKCH-LP-HAE-LMH009</p>	RI
		<p>Automated Genomic DNA extraction - QIASymphony SP, Extraction kit validated: SP DNA Midi Kit. And SOP PMKCH-LP-HAE-LMH076</p>	RI
		<p>DNA Quantification for QC purposes:</p> <p>FluoStar Omega</p> <p>SOP PMKCH-LP-HAE-LMH075</p>	RI
		<p>RNA Extraction with Trizol SOP PMKCH-LP-HAE-LMH075</p>	RI
		<p>cDNA preparation Reverse Transcriptase SOP PMKCH-LP-HAE-LMH005</p>	RI
	<p>BCR-ABL P210 Diagnosis and therapy monitoring</p>	<p>StepOnePlus real time PCR system SOP PMKCH-LP-HAE-LMH019</p>	RI



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	<u>Molecular Haemto-Oncology activities for the purpose of clinical diagnosis</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	BCR-ABL P190 Diagnosis and therapy monitoring	StepOnePlus real time PCR system SOP PMKCH-LP-HAE-LMH025	RI
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 PMKCH-LP-HAE-LMH047	RI
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 PMKCH-LP-HAE-LMH069	RI
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)	PCR using Veriti thermal cycler and Quantitative fragment analysis Applied Biosystems 3500XL Genetic analyser SOP PMKCH-LP-HAE-LMH018	RI



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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>Outputs from Next Generation Sequencer pipelines</p>	<p><u>Molecular Haemto-Oncology activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>BCR-ABL Tyrosine Kinase Diagnosis</p>	<p>Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:</p> <p>Next Generation Sequencing of PCR amplicons: Veriti Thermal cycler and Illumina Miseq-Next Generation Sequencer SOP PMKCH-LP-HAE-LMH067</p>	RI
	<p>Myeloproliferative Neoplasms JAK2 V617F JAK2 Exon 14 JAK2 Exon 12 CALR MPL</p>	<p>Custom Amplicon Sequencing using Veriti thermal cyclers and Illumina Adaptor and Indexing Methodology SOP PMKCH-LP-HAE-LMH081</p>	RI
	<p>Analysis of next generation sequencing</p>	<p>In-house developed pipeline Snappy with data displayed in the variant database SQVD. Variant scoring and sharing using VASA. SOPs PMKCH-LP-HAE-LMH077 and PMKCH-LP-HAE-LMH082</p>	RI



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cDNA synthesised in-house from the sample types listed above or received as primary sample type from an external source	<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:	RI
	Detection of <i>BCR-ABL1</i> fusion transcripts e13a2, e13a3, e14a2, e14a3, e1a2, e1a3, e19a2, e19a3, e6a2, e6a3, e8a2, e8a3, e18a2 and e18a3	Multiplex PCR using Veriti Thermal cyclers and non-quantitative fragment analysis Applied Biosystems 3500XL Genetic analyser SOP PMKCH-LP-HAE-LMH0073	
	gDNA extracted in-house from the sample types listed above or received as primary sample type from an external source.	FLT3 TKD, FLT3 ITD and NPM1 mutation analysis	Semi-quantitative fragment analysis Applied Biosystems 3500XL genetic analyser SOP PMKCH-LP-HAE-LMH084
gDNA extracted in-house from the sample types listed above or received as primary sample type from an external source.	<u>Cytogenetics Haemto-Oncology activities for the purpose of clinical diagnosis</u>		RI
	SNP Array Karyotyping	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 PMKCH-LP-HAE-LMH074 LMH Authorisation and Results Reporting PMKCH-LP-HAE-LMH059	



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<p>HUMAN TISSUES AND FLUIDS</p> <p>Bone Marrow Peripheral Blood Smears CSF Ascitic fluid Pleural Effusion</p>	<p><u>Cytogenetic analysis for the purpose of clinical diagnosis</u></p> <p>Detection of diagnostically and prognostically relevant cytogenetic abnormalities defined in the WHO Classification of Haematolymphoid Tumours (5th edition)</p> <p>Karyotyping</p>	<p>In house documented methods incorporating manufacturers' instructions as required</p> <p>Culturing of human tissues/cells using: Beckman Coulter 500 and LP-HAE-CYT-Booking In LP-HAE-CYT-BC500 LP-HAE-CYT-Set Up</p> <p>Preparation of cultured cells by manual harvest and G-banding for chromosome analysis using: LP-HAE-CYT-HRVST LP-HAE-CYT-Slide Prep LP-HAE-CYT-GBAND LP-HAE-CYT-MSLOAD</p> <p>Cell separation of CD138+ cells from Multiple Myeloma referrals using: LP-HAE-CYT-PCD</p> <p>Fluorescence In-situ Hybridisation (FISH) using commercial probes and: LP-HAE-CYT-FISH</p> <p>G-banded metaphase analysis using: LP-HAE-CYT-ANALYSIS</p> <p>Fluorescent In-Situ Hybridisation (FISH) analysis using: LP-HAE-CYT-ANALYSIS LP-HAE-CYT-FISHCAP</p>	<p>HW</p>
<p>Peripheral Blood</p>	<p>Constitutional analysis to confirm karyotyping findings</p>	<p>G-banded metaphase analysis & FISH analysis using: LP-HAE-CYT-ANALYSIS</p>	<p>HW</p>



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<p>HUMAN BODY FLUIDS</p> <p>Blood Bone Marrow</p>	<p><u>Haematology/Immunophenotyping examinations for the purpose of clinical diagnosis</u></p> <p>Immunophenotyping for Chronic T and B lymphoproliferative disorders:</p> <p>LST Tube: CD19 CD20 CD45 Kappa Lambda CD38 CD5 CD4 CD8 CD3 CD56</p> <p>B-cell follow on:</p> <p>Tube 1: CD19 CD81 CD23 CD79b CD10 CD200 CD43 CD45</p> <p>Tube 2: CD19 CD103 CD123 CD11c CD25 ROR1 CD45</p>	<p>In house documented methods incorporating manufacturers' instructions as required</p> <p>Becton Dickinson FACS Canto II Flow Cytometry of fluorescent labelled cells KCH-LP-HAE-IM1030 KCH-LP-HAE-IM1006 KCH-LP-HAE-IM1053</p>	<p>HW</p> <p>HW</p> <p>HW</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology/Immunophenotyping examinations for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions as required	
Blood Bone Marrow	T-cell follow on: Tube 1: CD57 CD2 CD16 CD7 CD25 CD3 HLADR CD45	Becton Dickinson FACS Canto II Flow Cytometry of fluorescent labelled cells KCH-LP-HAE-IM1030 KCH-LP-HAE-IM1006 KCH-LP-HAE-IM1053	HW
	Tube 2: TCR Alpha/Beta CD30 CD10 TCR Gamma/Delta CD3 CD4 CD45		HW
Blood Bone Marrow	Immunophenotyping for diagnosis of acute leukemia: Acute "Screen": CD8 Lambda CD13 Kappa CD34 CD33 CD3 HLADR CD117 CD4 CD19 CD45	Becton Dickinson FACS Canto II Flow Cytometry of fluorescent labelled cells KCH-LP-HAE-IM1030 KCH-LP-HAE-IM1006	HW



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HUMAN BODY FLUIDS (cont'd) Blood Bone Marrow	<u>Haematology/Immunophenotyping examinations for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions as required Becton Dickinson FACS Canto II Flow Cytometry of fluorescent labelled cells KCH-LP-HAE-IM1030 KCH-LP-HAE-IM1006	
	Tube 5: CD61/CD42 CD123 CD7 CD4		HW
	B-ALL: Tube 1: CD58 CD66c CD34 CD10 CD38 CD20 CD45 CD19		HW
	Tube 2: TDT NG2 CD34 CD13 CD19 HLADR CD123 CD45		HW
	T-ALL		HW
	Tube 1 TDT CD1A CD5 CD10 CD8 CD3 CD4 CD45		HW



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Blood Bone Marrow	Tube 2: CD2 CD99 CD5 CD7 TCR gamma delta CD3 CD123 CD45 Minimal Residual Disease (MRD) assessment of:	Becton Dickinson FACS Canto II Flow Cytometry of fluorescent labelled cells KCH-LP- HAE-IM1123 KCH-LP-HAE-IM1122	HW
	B-acute lymphoblastic leukaemia: CD58 CD66c CD34 CD10 CD38 CD20 CD45 CD19		HW
	Chronic lymphocytic leukaemia: CD81 CD79b CD5 ROR 1 CD19 CD20 CD43 CD45		HW



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology/Immunophenotyping examinations for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions as required	
	Acute myeloid leukaemia: CD34 CD117 CD45 HLADR CD13 CD33 CD11b CD2 CD5 CD38 CD123 CD19 CD36 CD56 CD7 CD64	KCH-LP-HAE-IM-1125	HW
Blood Bone Marrow	Immunophenotyping for the diagnosis of Plasma cell disorders: CD27 CD56 CD5 CD138 CD38 CD20 CD45 CD19	Becton Dickinson FACS Canto II Flow Cytometry of fluorescent labelled cells GEN-KD-HMDS-IMMPH-IM1108	HW
	Cyt Kappa / Cyt Lambda CD117 CD138 CD38 CD45 CD19		HW



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Blood Bone Marrow</p>	<p><u>Haematology/Immunophenotyping examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Testing for Paroxysmal Nocturnal Haemoglobinuria (PNH):</p> <p>WBC: CD157 FLAER CD64 CD15 CD45</p> <p>RBC: CD59 CD235a</p>	<p>In house documented methods incorporating manufacturers' instructions as required</p> <p>Becton Dickinson FACS Canto II Flow Cytometry of fluorescent labelled cells KCH-LP-HAE-IM1030 KCH-LP-HAE-IM1006</p>	<p>HW</p> <p>HW</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology/Immunophenotyping examinations for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions as required	
Blood Bone Marrow	Immunophenotyping for Myelodysplastic Syndrome (MDS) assessment: CD34 CD117 CD45 HLADR CD16 CD10 CD11b CD13 CD14 CD64 IREM2 CD38 CD19 CD56 CD15 CD71 CD36 CD33 CD7 CD123 CD4	Becton Dickinson FACS Canto II Flow Cytometry of fluorescent labelled cells KCH-LP-HAE-IM1126	HW
Bone marrow aspirates	Iron deposits haemosiderin	Thermo Scientific Gemini AS Auto stainer and the Sigma-Aldrich Hematognost Fe staining kit. LP-HAE-IM1141	HW
END			