Schedule of Accreditation

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Accredited to ISO 15189:2022

Synnovis Analytics LLP

Issue No: 015 **Issue date:** 27 March 2025

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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
	Molecular Haemto-Oncology activities for the purpose of clinical diagnosis	Procedures documented in manufacturer's equipment manuals in conjunction with documented in- house procedures by the following methods:
Fresh, frozen or fixed human tissue or cells (Blood and Bone marrow)		Genomic DNA extraction Manual Extraction (Qiagen) SOP LP-HAE-LMH009
Fresh Peripheral Blood, Fresh Bone Marrow, Frozen Peripheral Blood, Frozen Bone Marrow, Specific Cell lineages extracted from fresh blood (CD3, 15, 19)		Automated Genomic DNA extraction - QIAsymphony SP, Extraction kit validated: SP DNA Midi Kit. And SOP LP-HAE-LMH076
Genomic DNA extracted in-house from the sample types listed above or received as primary sample type from an external source		DNA Quantification for QC purposes: FluoStar Omega SOP LP-HAE-LMH075
Fresh cells (Blood and Bone marrow)		RNA Extraction with Trizol SOP LP-HAE-LMH001
RNA		cDNA preparation Reverse Transcriptase SOP LP-HAE-LMH005
cDNA synthesised in-house from the sample types listed above or received as primary sample type from an external source	BCR-ABL P210 Diagnosis and therapy monitoring	StepOnePlus real time PCR system SOP LP-HAE-LMH019
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 LP-HAE-LMH025

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
	Molecular Haemto-Oncology activities for the purpose of clinical diagnosis (cont'd)	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 and therapy monitoring	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)	PCR using Veriti thermal cycler and Quantitative fragment analysis Applied Biosystems 3500XL Genetic analyser SOP LP-HAE-LMH018

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
	Molecular Haemto-Oncology activities for the purpose of clinical diagnosis (cont'd)	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. 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 Diagnosis	Next Generation Sequencing of PCR amplicons: Veriti Thermal cycler and 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 Veriti thermal cyclers and 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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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
	Molecular Haemto-Oncology activities for the purpose of clinical diagnosis (cont'd)	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	Detection of *BCR-ABL1* 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 LP-HAE-LMH0073
Blood and bone marrow	FLT3 TKD, FLT3 ITD and NPM1 mutation analysis	Semi-quantitative fragment analysis Applied Biosystems 3500XL genetic analyser SOP LP-HAE-LMH084
	Cytogenetics Haemto-Oncology activities for the purpose of clinical diagnosis	
gDNA extracted in-house from the sample types listed above or received as primary sample type from an external source.	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 (LP-HAE-LMH074) LMH Authorisation and Results Reporting (LP-HAE-LMH059
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