Schedule of Accreditation

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UKAS MEDICAL **9305** **Accredited to ISO 15189:2022**	**Leeds Teaching Hospitals NHS Trust** **Issue No:** 010 **Issue date:** 06 June 2025	
	Haematological Malignancy Diagnostic Service **St. James' University Hospital** **Leeds** **LS9 7TF** **United Kingdom**	**Contact: Dr Catherine Cargo / Dr Ruth De Tute** **Tel: +44 (0)1132067963** **Fax: +44 (0)1132067883** **E-Mail: catherine.cargo@nhs.net / rdetute@nhs.net** **Website: www.hmds.info**
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
HUMAN BODY TISSUE AND FLUIDS	Histopathology examination activities in order to identify or exclude morphological abnormalities for the purpose of haematological malignancy diagnosis	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:
Tissue		Tissue dissection: Morphology SOP HP01, HP39 Decalcification SOP HP44 Tissue processing/embedding (paraffin): Thermo Scientific Excelsior AS tissue processor & Leica HistoCore Arcadia H embedding centre SOP HP04
Tissue within paraffin blocks (produced using procedures above or received as a primary sample type)		Microtomy (paraffin blocks): Microm HM325 & Leica HistoCore Autocut microtomes, water baths, hot-plates SOP HP06, HP32

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Histopathology examination activities in order to identify or exclude morphological abnormalities for the purpose of haematological malignancy diagnosis (cont'd)	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:
Paraffin (produced using procedures above or received as a primary sample type) embedded tissue	Identification of:	
	Basophilic and eosinophilic structures	Automated Haematoxylin & Eosin and May Grunwald Giemsa Sakura Prisma Stainer & Film Coverslipper. SOP HP45 Manual Special tinctorial staining: Sakura Prisma Stainer & Film Coverslipper. SOP HP45
	Amyloid	Congo Red (HP21)
	Differentiation of different haemopoietic cells	May Grunwald Giemsa (HP13)
	Reticulin fibres	Reticulin (Gordon & Sweets) (HP12)
	Tubercle bacilli	Ziehl-Neelsen (HP15)
	Identification of:	Immunohistochemistry: Dako Autostainers, Dako Omnis, Manual staining SOP HP27, HP40, HP42 Using the following monoclonal and polyclonal antibodies:
	T-cells, mantle zone B-cells , follicular lymphomas	Bcl-2 (clones 124 & E17)
	Germinal centre B-cells & related lymphomas	Bcl-6
	Activated B-cells, plasma cells	Blimp-1

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Histopathology examination activities in order to identify or exclude morphological abnormalities for the purpose of haematological malignancy diagnosis (cont'd)	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:
	Identification of: (cont'd)	Immunohistochemistry: Dako Autostainers, Dako Omnis, Manual staining SOP HP27, HP40, HP42 Using the following monoclonal and polyclonal antibodies:
	Langerhan's cells, interdigitating dendritic cells, associated disease states	CD1a
	Pan T-cell marker & T-cell lymphomas	CD2
	Pan T-cell marker & T-cell lymphomas	CD3
	T-helper cells & related lymphoma	CD4
	T-cells, mantle zone B-cells, neoplastic B-cells (CLL, MCL), T-cell lymphomas	CD5
	Early T-cells & NK cells, related T-cell lymphomas	CD7
	Mature suppressor / cytotoxic T-cells, associated T-cell lymphomas	CD8
	Germinal centre B cells & related lymphomas	CD10
	Monocytes, macrophages, Hairy Cell Leukaemia cells	CD11c
	Myeloid cells, Reed Sternberg cells	CD15
	B-cells & associated B-Cell lymphomas, normal plasma cells	CD19
	B-cells & associated B-Cell lymphomas	CD20

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Histopathology examination activities in order to identify or exclude morphological abnormalities for the purpose of haematological malignancy diagnosis (cont'd)	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:
	Identification of: (cont'd)	Immunohistochemistry: Dako Autostainers, Dako Omnis, Manual staining SOP HP27, HP40, HP42 Using the following monoclonal and polyclonal antibodies:
	Follicular dendritic cells, mature B-cells	CD21
	B-cells, associated B-cell lymphomas	CD22
	Follicular dendritic cells, B-cells, CLL cells	CD23
	Activated T-cells, inter-leukin-2 receptor cells	CD25
	Activated B & T-cells, Reed Sternberg / Hodgkin's cells	CD30
	Endothelial cells, blast cells	CD34
	Pan Leucocyte marker- normal & neoplastic cells	CD45
	NK cells, nerve cells, neuroblastomas, some neoplastic PCs	CD56
	NK cells, related lymphomas	CD57
	Megakaryocytes, megakaryocytes precursors, and platelets	CD61
	Macrophages & myeloid cells	CD68
	B-cells & associated B-Cell lymphomas	CD79a
	Ewings sarcoma, lymphocytes	CD99

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Histopathology examination activities in order to identify or exclude morphological abnormalities for the purpose of haematological malignancy diagnosis (cont'd)	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:
	Identification of: (cont'd)	Immunohistochemistry: Dako Autostainers, Dako Omnis, Manual staining SOP HP27, HP40, HP42 Using the following monoclonal and polyclonal antibodies:
	Melanocytes, mast cells, AML tumour cells, GIST	CD117 C-KIT
	Kikuchi disease	CD123
	Normal & neoplastic plasma cells, epithelial cells	CD138
	Assist in identification of positive cells in myeloid sarcomas and T-ALL	CD13
	Macrophages, monocytes	CD163
	Alk + tumours (ALCL)	CD246
	Plasma cells, plasmacytic lymphoma vs myeloma	CD319 (manual staining only)
	Normal & neoplastic epithelial cells (instestinal)	CDX2
	Identification of myeloid sarcomas and T-ALL	CD33
	Normal & neoplastic epithelia (breast)	CK 7
	Normal & neoplastic epithelia (colon)	CK20
	Cells showing Myc translocation, disease related	C Myc
	Epithelial cells, Mantle cell lymphoma	Cyclin D1
	Broad spectrum of normal & neoplastic epithelia	Cytokeratin - Cam 5.2

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Histopathology examination activities in order to identify or exclude morphological abnormalities for the purpose of haematological malignancy diagnosis (cont'd)	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:
	Identification of: (cont'd)	Immunohistochemistry: Dako Autostainers, Dako Omnis, Manual staining SOP HP27, HP40, HP42 Using the following monoclonal and polyclonal antibodies:
	Broad spectrum of normal & neoplastic epithelia	Cytokeratin - MNF116
	Follicular helper T-cells, angioblastic T-cell lymphomas	CXCL13
	Suggestive of Hairy Cell Leukaemia	Leukaemia Hairy cell (DBA44)
	Smooth & striated muscle	Desmin
	Endothelial cells, Megakaryocytes	Factor VIII
	Erythroid cells & precursors	Glycophorin C
	Cytotoxic T-cells & NK cells & related lymphomas	Granzyme B
	Karposi sarcoma virus, associated multicentric Castleman's disease	HHV8
	IgA expressing plasma cells	IgA (manual staining only)
	IgD expressing plasma cells, Mantle zone B-cells	IgD
	IgG expressing plasma cells & lymphocytes	IgG (manual staining only)
	Specific subtype of plasma cells, IgG4 disease	IgG4 (manual staining only)

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Histopathology examination activities in order to identify or exclude morphological abnormalities for the purpose of haematological malignancy diagnosis (cont'd)	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:
	Identification of: (cont'd)	Immunohistochemistry: Dako Autostainers, Dako Omnis, Manual staining SOP HP27, HP40, HP42 Using the following monoclonal and polyclonal antibodies:
	IgM expressing plasma cells, mantle zone B-cells	IgM (manual staining only)
	Plasma cells, activated T-cells, some germinal centre B-cells, R/S cells & associated lymphomas	IRF4
	Kappa light chain expressing plasma cells and lymphoid cells (mantle zone B-cells)	Kappa (manual staining only)
	Lambda light chain expressing plasma cells and lymphoid cells (mantle zone B-cells)	Lambda (manual staining only)
	Langerhan's cells, IRDC's	Langerin
	Diagnosis of follicular lymphoma	LMO2
	EBV	LMP-1
	Histiocytes	Lysozyme
	Mast cells, related disorders	Mast-cell tryptase
	Melanoma cells	Melanoma monoclonal
	Proliferating cells	MIB1
	Myeloid cells	Myeloperoxidase
	Rhabdomyosarcoma cells	Myo D1
	Rhabdomyosarcoma & Ewings tumour cells	Myogenin

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Histopathology examination activities in order to identify or exclude morphological abnormalities for the purpose of haematological malignancy diagnosis (cont'd)	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:
	Identification of: (cont'd)	Immunohistochemistry: Dako Autostainers, Dako Omnis, Manual staining SOP HP27, HP40, HP42 Using the following monoclonal and polyclonal antibodies:
	B-cells, Germinal centre cells, plasma cells	OCT-2
	Embryonic cells & germ cells & related diseases	OCT-3/4
	B-cells	PAX-5
	Follicular Helper T-cells	PD1
	Neural cells, neuroblastoma cells	PGP 9.5
	Prostate glandular tissue, related carcinomas	PSMA
	Transcription factor, monocytic lineage, early granulocytes	PU-1
	Neural cells, melanocytes	S100
	Mantle cell lymphoma	SOX-11
	Normal T & B-lymphocyte precursors. T-ALL & B-ALL cells	TDT

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS/TISSUE Whole Blood Bone Marrow Whole Blood Bone Marrow Whole Blood Bone Marrow Separated cells from blood and bone marrow Fixed Cells Effusions CSF Vitreous biopsies	<u>Genomics analysis for the purpose of clinical diagnosis, prognosis, and patient management</u> Sample processing, DNA and RNA extraction, quantification and quality check for subsequent in-house analysis (see below), referral to specialist centres and long term storage	In house documented methods incorporating manufacturers' instructions where relevant Manual and Automated separation of cell fractions **Automated** Separation of cell fractions: Using Miltenyi Automacs Pro SOP FC028 **Manual** Separation of lineage specific fractions Using: Dynal Magnetic Separator SOP MH05 Manual and semi-automated and automated DNA extraction and quantification using: **Semi-Automated Extraction** Qiagen QIAcube with Qiagen QIAamp DNA Blood Mini Kit SOP MH02 SOP MH62

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS/TISSUE (cont'd)	Genomics analysis for the purpose of clinical diagnosis, prognosis, and patient management (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant
FFPE Tissue Slide Sections Fresh Solid Tissue		**Semi-Automated Extraction (cont)** Qiagen QIAcube with Qiagen QIAamp DNA FFPE Tissue Kit SOP MH02 SOP MH62
Genomic DNA extracted in-house from or received as primary sample type from an external source		DNA Quantification for QC purposes using: Promega Glomax 96 well fluorimeter SOP MH62
	RNA extraction and preparation of cDNA, for subsequent in-house analysis (see below), referral to specialist centres and long term storage	Manual and semi-automated RNA extraction, conversion to cDNA and quantification using:
Whole Blood Bone Marrow Separated Cells from Blood and Bone Marrow		Manual methods: Qiagen RNeasy Mini Kit SOP MH02 Semi-Automated methods: Promega Maxwell RSC and Maxwell RSC simplyRNA blood kit SOP MH02

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS/TISSUE (cont'd)	Genomics analysis for the purpose of clinical diagnosis, prognosis, and patient management (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant **Reverse Transcription** Manual method using Invitrogen M-MLV reverse transcriptase, thermal cycler and UV cross linker SOP MH02 **Sanger Sequencing**
Genomic DNA extracted in-house from the sample types listed above or received as primary sample type from an external source	Detection of nucleic acid sequence variants - SNVs and small indels [Definitive list HMDS4406]	Using: Standard primer design methodology using SOP MH75 And PCR using thermal cyclers Sanger Sequencing by: (Applied Biosystems (ABI) Analysers 3500 Analysis using Mutation Surveyor SOP MH74

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS/TISSUE (cont'd)	Genomics analysis for the purpose of clinical diagnosis, prognosis, and patient management (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant **Fragment Analysis**
Genomic DNA extracted in-house from the sample types listed above or received as primary sample type from an external source	Determination of fragment length size and detection of deletions, known SNVs and indels, gene rearrangements, internal tandem duplications and microsatellites [Definitive list HMDS4407]	Fluorescent Based Fragment Analysis Using Commercial Kits: Powerplex 16 – Chimerism Invivoscribe – TCRB only In-house Using: Standard primer design methodology (including TCR) (SOP MH75) And PCR (including multiplex PCR) with Fluorescent fragment analysis using ABI 3500 Genetic Analyzer. Analysis using Genemapper and Chimermarker SOPs MH11 MH14 MH19 MH36 MH56

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS/TISSUE (cont'd)	Genomics analysis for the purpose of clinical diagnosis, prognosis, and patient management (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant
Genomic DNA extracted in-house from the sample types listed above or received as primary sample type from an external source	Fragments sizing for detection of known SNVs [Definitive list HMDS4407]	Fluorescent based PCR amplification followed by restriction enzyme digest In house methodology with thermal cyclers and ABI 3500 Genetic Analyzer Analysis using Genemapper SOP: MH11
Genomic DNA extracted in-house from the sample types listed above or received as primary sample type from an external source	Detection of known SNVs and small indels [Definitive list HMDS4407]	Gel Electrophoresis based Fragment Analysis Using: Standard primer design methodology And PCR or allele specific PCR using Thermal cyclers Resolution with Agarose gel electrophoresis and visualisation using UVP UV transilluminator 312nm, Cannon Powershot digital camera capture system and software. SOP MH08 MH47 MH57 MH58

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS/TISSUE (cont'd)	Genomics analysis for the purpose of clinical diagnosis, prognosis, and patient management (cont'd)	**In house documented methods incorporating manufacturers' instructions where relevant** **Fragment Analysis for Multiplex Ligation-dependent Probe Amplification (MLPA)**
Genomic DNA extracted in-house from the sample types listed above or received as primary sample type from an external source	Detection of whole exon deletions/duplications [Definitive list HMDS4408]	Multiplex Ligation Probe Analysis (MLPA) using: Commercial commercial MRC Holland kits and Thermal cyclers and ABI 3500 Genetic Analyzer Analysis using Coffalyser Analysis Software SOPs MH81 MH82
cDNA derived from RNA extracted and reverse transcribed in-house from blood and bone marrow, or received as primary sample type from an external source	Detection of fusion gene transcripts and determination of breakpoint regions [Definitive list HMDS4409]	**Qualitative Real Time PCR** In house methodology. Real time PCR using Applied Biosystems Realtime 7500 analyser Analysis using 7500 analyser software SOPs MH35 MH55

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS/TISSUE (cont'd)	Genomics analysis for the purpose of clinical diagnosis, prognosis, and patient management (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant
cDNA received as primary sample type or derived from RNA extracted and reverse transcribed in-house from blood and bone marrow	Quantification of major breakpoint regions in *BCR-ABL1* fusion transcripts [Definitive list: HMDS4409]	**Quantitative Real Time PCR** In house real time PCR methodology with EAC primers and probes. Ipsogen Qiagen plasmids standard curve used for quantitative assay Quantification using Applied Biosystems Realtime 7500 analyser Analysis using 7500 analyser software SOPs MH35 MH55
cDNA received as primary sample type or derived from RNA extracted and reverse transcribed in-house from blood and bone marrow	Quantification of breakpoint regions of fusion transcripts [Definitive list HMDS4409]	In house real time PCR methodology with EAC primers and probes. Ipsogen Qiagen plasmids standard curve used for quantitative assay Quantification using Applied Biosystems Realtime 7500 analyser and Quantstudio 3 Analysis using analyser software SOPs: MH88
cDNA received as primary sample type or derived from RNA extracted and reverse transcribed in-house from blood and bone marrow	Quantification of SNVs and small indels [Definitive list HMDS4409]	Real time PCR using ipsogen NPM1 MutaQuant Kits Quantification using Applied Biosystems Realtime 7500 and analysis using 7500 software SOPs: MH88

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS/TISSUE (cont'd)	Genomics analysis for the purpose of clinical diagnosis, prognosis, and patient management (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant **Next Generation Sequencing**
Genomic DNA extracted in-house from the sample types listed above or received as primary sample type from an external source	Screening of large targeted single or multigene panels for genetic variants [Definitive list HMDS4410] SNVs and small indels	Targeted amplicon library preparation Fluidigm 48:48 access array with High Throughput Sequencing Using Thermal cyclers and Illumina MiSeq Analysis using in-house Bioinformatics pipeline SOPs MH78 MH83 BI001 BI002 BI003 BI004
Genomic DNA extracted in-house from the sample types listed above or received as primary sample type from an external source	Screening of large targeted single or multigene panels for genetic variants [Definitive list HMDS4410] SNVs and small indels	Library Preparation using Twist enzymatic fragmentation and Custom Twist probes Using Thernak cyclers and NextSeq 550 DX Analysis and interpretation using in-house Bioinformatics pipeline and HaemOncDB v4 respectively SOPs: MH87 BI010 BI011 BI012 YNEGLH004 YNEGLH002

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS/TISSUE (cont'd)	Genomics analysis for the purpose of clinical diagnosis, prognosis, and patient management (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant
Genomic DNA from whole blood and bone marrow or received as primary sample type from an external source	Screening of large targeted single or multigene panels for genetic variants [Definitive list HMDS4410] SNVs and small indels	Targeted amplicon library preparation Using Thermal cyclers and Ion GS-S5-PR Sequencer & Ion Chef Analysis and interpretation using in-house Bioinformatics pipeline Analysis steps from base-calling to variant-calling are carried out using ThermoFisher proprietary software on the Torrent Server QC, filtering and analysis using In house HaemOncDB v4 SOPs: MH91 BI010 BI011 BI012 BI014 BI015 YNEGLH001 YNEGLH004 YNEGLH005 YNEGLH010 YNEGLH011
Genomic DNA extracted in-house from the sample types listed above or received as primary sample type from an external source	Detection of nucleic acid sequence variants - SNVs and small indels [Definitive list HMDS4846]	Droplet digital PCR MH92MH93

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS/TISSUE (cont'd)	Genomics analysis for the purpose of clinical diagnosis, prognosis, and patient management (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant
Paraffin embedded tissue Bone marrow smears Perpheral Blood smears Tissue imprint/Dab Methanol:acetic acid fixed cell suspensions Ammonium chloride lysed BM and PB CD138+ plasma cell selections Bone marrow aspirate, peripheral blood, fresh tissue imprints	Detection and analysis of genomic rearrangements and imbalances in: Haemato-Oncological disorders Bone Marrow failure Identification/Confirmation of genomic rearrangements, gains and losses – using Locus specific probes: Break apart Dual colour dual fusion Copy Number/Amplification	**Fluorescent in-situ hybridisation (FISH)** Separation of cell fractions using Miltenyi Automacs Pro Mannual FISH: FISH performed using commercial probes, CytoBrite Slide Incubation System, MicroFISH Hybridization Oven Grant HotPlate, Clifton waterbaths, microwave, pressure cooker, microfuge and pipettes.
FFPE Bone marrow smears, MAA fixed haematologically-derived cell suspensions	ALK Breakapart IGH/MAFB	
FFPE Samples	[Definitive list of probes HMDS4504]	Automated FISH: FISH performed using Dako OMNIS automated platform using commercial probes. Analysis using: Cytovision analysis software and and Leica fluorescent microscope system SOPs F001 F002 F005 FC028

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS/TISSUE (cont'd)	Genomics analysis for the purpose of clinical diagnosis, prognosis, and patient management (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant
FFPE	Detection of EBV infection in B-Cell lymphoproliferative disorders	**In-situ hybridisation** ISH performed using Dako EBV (EBER) probe (with Dako PNA ISH Detection Kit CytoBrite Slide Incubation System, MicroFISH Hybridization Oven Grant HotPlate, Clifton waterbaths, microwave, microfuge and pipettes. Analysis using Light Microscopy SOP F004
SNP array data files received from an external source within the YNEGLH	Detection of DNA copy number variation and loss of heterozygosity.	**SNP Array – Data analysis only:** Analysis and interpretation of SNP array data using BlueFuse Multi and web-based UCSC genome browser. SOP MH66

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS	Haematology examinations for the purpose of haematological malignancy diagnosis	Documented in house methods incorporating manufacturers' instructions where relevant:
Blood, bone marrow aspirate, CSF, Effusions	Morphological assessment of haematopoietic cells	Automated May Grunwald Giemsa staining using Aerospray Haematology Stainer. SOP GEN28
Blood, bone marrow aspirate, CSF, Effusions	Full blood count: White blood cell count (WBC), red cell count (RBC), Haemoglobin (HGB), Haematocrit (HCT), Mean cell volume (MCV), Mean cell haemoglobin (MCH), Mean cell haemoglobin concentration (MCHC), Lymphocyte percentage/ count (LYM%/LYM#), Neutrophil percentage/count (NEUT%/#) and Mixed population percentage/Count (MXD%/#)	Sysmex XP-300 blood analyser, SOP GEN001, GEN 004, GEN005 GEN011, GEN016, GEN021
Blood	Blood film - cell typing and morphology, manual White Blood Cell Differential for enumeration of cell types	Thermo Scientific cytospin 4, Leica stainer using May Grunwald Giemsa Stain Light microscopy SOP GEN001, GEN 004, GEN005 GEN011, GEN016, GEN021

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Haematology examinations for the purpose of haematological malignancy diagnosis (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant:
Blood, bone marrow aspirate CSF, effusions, histological tissue	Immunophenotyping of the following markers/antigens to screen for, diagnose or monitor: Acute leukaemia - AML/B-ALL/T-ALL Chronic myeloid disorders - MDS/CML/CMML B- & T- lymphoproliferative disorders Myeloma/MGUS	Flow cytometry on Becton Dickinson FACS Canto II using defined monoclonal antibody panels SOP FC001 - 003, FC022-025, FC027, GEN006 SOP FC004-011, FC026
	Stem Cell Screen (SCS): CD64 CD45 CD38 CD10 CD19 CD117 CD34 HLA-DR	8 colours
	B-cell screen (BLS): CD19 CD20 CD5 CD10 CD305 (LAIR-1) CD45 Kappa Lambda	8 colours
	T-cell screen (TLS): CD3 CD4 CD8 CD16/CD56 CD45 CD7 CD5 HLA-DR	8 colours

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Haematology examinations for the purpose of haematological malignancy diagnosis (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant:
Blood, bone marrow aspirate CSF, effusions, histological tissue (cont'd)	Immunophenotyping of the following markers/antigens to screen for, diagnose or monitor: Acute leukaemia - AML/B-ALL/T-ALL Chronic myeloid disorders - MDS/CML/CMML B- & T- lymphoproliferative disorders Myeloma/MGUS (cont'd)	Flow cytometry on Becton Dickinson FACS Canto II using defined monoclonal antibody panels SOP FC001 - 003, FC022-025, FC027, GEN006 SOP FC004-011, FC026
	Plasma cell screen: CD38 CD138 CD19 CD45 CD56 CD117 CD27 CD81	8 colours
	Outreach monitoring (CMP): CD19 CD38 CD45 CD5 Kappa Lambda	6 colours
	Rituximab monitoring: CD3 CD14 CD19 CD38 CD27 CD45	6 colours

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Haematology examinations for the purpose of haematological malignancy diagnosis (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant:
Blood, bone marrow aspirate CSF, effusions, histological tissue	Immunophenotyping of the following markers/antigens in an 8-colour panel to diagnose and monitor myeloid disorders (AML, MDS, CMML) TdT MPO CD33 CD117 CD34 CD45 CD79a CD3 CD38 CD56 CD13 CD7 CD11b CD10 CD16 CD15 CD300e CD14 CD64 HLA-DR CD36 CD235a CD105 CD71 CD61 CD2 NG2 CD123 CD25 CD4	Flow cytometry performed on Becton Dickinson Facs Lyric instrument using defined monoclonal antibody panels SOP FC022-025 & 027, GEN006 SOP FC013

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Haematology examinations for the purpose of haematological malignancy diagnosis (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant:
Blood, bone marrow aspirate CSF, effusions, histological tissue (cont'd)	Immunophenotyping of the following markers/antigens to diagnose and monitor Acute lymphoblastic leukaemia (B-ALL & T-ALL)	Flow cytometry performed on Facs Lyric instrument using defined monoclonal antibody panels SOP FC022-025, 027, GEN006 SOP FC015 & FC017
	B-ALL: TdT MPO CD33 CD117 CD34 CD45 CD79a CD3 CD66c CD123 CD304 CD73 CD81 CD13 CD33 CD34 CD19 CD10 CD45 CD38 CD79b CD86 CD9 CD58 CD24 CD44 CD22 HLA-DR NG2 CD20 CD15	8 colours

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Haematology examinations for the purpose of haematological malignancy diagnosis</u> (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant:
Blood, bone marrow aspirate CSF, effusions, histological tissue (cont'd)	Immunophenotyping of the following markers/antigens to diagnose and monitor Acute lymphoblastic leukaemia (B-ALL & T-ALL) (cont'd) T-ALL: CD3 CD1a CD2 CD4 CD5 CD7 CD8 CD10 CD16 CD25 CD27 CD45 CD45RA CD56 CD57 HLA-DR TCR$\alpha\beta$ TCR$\gamma\delta$ Tdt MPO CD79a CD33 CD117 CD34	Flow cytometry performed on Facs Lyric instrument using defined monoclonal antibody panels SOP FC022-025, 027, GEN006 SOP FC015 & FC017 6 colours

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Haematology examinations for the purpose of haematological malignancy diagnosis (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant:
Blood, bone marrow aspirate CSF, effusions, histological tissue (cont'd)	Immunophenotyping of the following markers/antigens to diagnose and monitor mature B- and T-cell lymphoproliferative disorders:	Flow cytometry on Becton Dickinson FACS Canto II using defined monoclonal antibody panels SOP FC001 - 003, FC022-025, FC027, GEN006 FC011, FC019
	Extended B-cell panel: CD19 CD20 CD23 CD43 CD81 CD79b CD5 ROR1 CD95 CD31 CD49d CD305 (LAIR-1) CD38 CD10 CD25 CD11c CD103 CD200 CD39 CD22 CD196 CD185 IgG IgD IgM CD27	8 colours

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Haematology examinations for the purpose of haematological malignancy diagnosis (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant:
Blood, bone marrow aspirate CSF, effusions, histological tissue (cont'd)	Immunophenotyping of the following markers/antigens to diagnose and monitor mature B- and T-cell lymphoproliferative disorders:	Flow cytometry on Becton Dickinson FACS Canto II using defined monoclonal antibody panels SOP FC001 - 003, FC022-025, FC027, GEN006 FC011, FC019
	Extended T-cell panel: CD3 CD1a CD2 CD4 CD5 CD7 CD8 CD10 CD16 CD25 CD27 CD45 CD45RA CD52 CD56 CD57 HLA-DR TCR$\alpha\beta$ TCR$\gamma\delta$ CD14	6 colours

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Haematology examinations for the purpose of haematological malignancy diagnosis (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant:
Blood	Immunophenotyping of the following markers/antigens to assess the deficiency of GPI linked antigens on red blood cells and leucocytes (PNH panel)	Flow cytometry performed on Becton Dickinson Facs Lyric instrument using defined monoclonal antibody panels SOP FC020 SOP FC032
	Red blood cells: CD235a CD59 CD71 CD3d	4 Colours
	Leucocytes: CD16 CD15 CD14 CD24 CD33 Flaer Alexa-488 CD157	8 Colours
Blood/Bone Marrow/CSF	Identification of normal or aberrant PML protein expression pattern in suspected cases of Acute Promyelocytic Leukaemia	Immunofluorescence; Cytovision analysis software and and Leica fluorescent microscope system SOP IMM006
Histology and haematology slides prepared as above	Morphological assessment and interpretation/diagnosis	Microscopy SOP R1, OFF002
END		