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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
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 HP01 Tissue processing/embedding (paraffin): Thermo Shandon Excelsior ES tissue processor & Thermo Shandon embedding centre SOP HP04
Tissue within paraffin blocks (produced using procedures above or received as a primary sample type) Bone marrow trephine biopsies		Microtomy (paraffin blocks): Microm microtomes, water baths, hot-plates SOP HP06, HP32 Manual tissue processing/embedding (resin): Specimen rotators, SOP HP03
Bone marrow trephine biopsies within resin blocks (produced using procedure above)		Microtomy (resin blocks): Riechert Autocut microtomes, Leica Glass knife maker SOP HP07

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) and resin (produced using procedures above) embedded tissue	Identification of: Nuclei and other cellular components and tissue structures	Manual Haematoxylin and Eosin staining: Microm coverslipper, light microscope SOP HP11
	Identification of:	Manual Special tinctorial staining: Microm coverslipper, light microscope SOP HP12, HP13, HP14, HP15, HP19, HP21
	Amyloid	Congo Red (HP21)
	Differentiation of different haemopoietic cells	May Grunwald Giemsa (HP13)
	Glycogen (and other PAS positive substances)	PAS (+/- diastase) (HP19)
	Heamosiderin	Perls' (HP14)
	Reticulin fibres	Reticulin (Gordon & Sweets) (HP12)
	Tubercle bacilli	Ziehl-Neelsen (HP15)
	Identification of:	Immunohistochemistry: Dako Autostainers, Dako Omnis, pressure cooker / microwave 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, pressure cooker / microwave SOP HP27, HP40, HP42 Using the following monoclonal and polyclonal antibodies:
	B-cells, Germinal centre cells, plasma cells	BOB-1
	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

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, pressure cooker / microwave SOP HP27, HP40, HP42 Using the following monoclonal and polyclonal antibodies:
	B-cells & associated B-Cell lymphomas, normal plasma cells	CD19
	B-cells & associated B-Cell lymphomas	CD20
	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
	Plasma cells	CD38
	Pan Leucocyte marker- normal & neoplastic cells	CD45
	NK cells, nerve cells, neuroblastomas, some neoplastic PCs	CD56
	NK cells, related lymphomas	CD57

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, pressure cooker / microwave SOP HP27, HP40, HP42 Using the following monoclonal and polyclonal antibodies:
	Macrophages & myeloid cells	CD68
	B-cells & associated B-Cell lymphomas	CD79a
	Ewings sarcoma, lymphocytes	CD99
	Melanocytes, mast cells, AML tumour cells, GIST	CD117 C-KIT
	Kikuchi disease	CD123
	Normal & neoplastic plasma cells, epithelial cells	CD138
	Macrophages, monocytes	CD163
	Alk + tumours (ALCL)	CD246
	Plasma cells, plasmacytic lymphoma vs myeloma	CD319
	Normal & neoplastic epithelial cells (instestinal)	CDX2
	Normal & neoplastic epithelia (breast)	CK 7
	Normal & neoplastic epithelia (colon)	CK20
	Cells showing Myc translocation, disease related	C Myc

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, pressure cooker / microwave SOP HP27, HP40, HP42 Using the following monoclonal and polyclonal antibodies:
	Epithelial cells, Mantle cell lymphoma	Cyclin D1
	Broad spectrum of normal & neoplastic epithelia	Cytokeratin - Cam 5.2
	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
	Post germinal centre B-cells	FOXP1
	Erythroid cells & precursors	Glycophorin C
	Cytotoxic T-cells & NK cells & related lymphomas	Granzyme B
	HLA class II DR antigen expressing cells	HLA-DR
	Karposi sarcoma virus, associated multicentric Castleman's disease	HHV8
	IgA expressing plasma cells	IgA

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, pressure cooker / microwave SOP HP27, HP40, HP42 Using the following monoclonal and polyclonal antibodies:
	IgD expressing plasma cells, Mantle zone B-cells	IgD
	IgG expressing plasma cells & lymphocytes	IgG
	Specific subtype of plasma cells, IgG4 disease	IgG4
	IgM expressing plasma cells, mantle zone B-cells	IgM
	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
	Lambda light chain expressing plasma cells and lymphoid cells (mantle zone B-cells)	Lambda
	Langerhan's cells, IRDC's	Langerin
	EBV	LMP-1
	Histiocytes	Lysozyme
	Mast cells, related disorders	Mast-cell tryptase
	Melanoma cells	Melanoma monoclonal

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, pressure cooker / microwave SOP HP27, HP40, HP42 Using the following monoclonal and polyclonal antibodies:
	Proliferating cells	MIB1
	Myeloid cells	Myeloperoxidase
	Rhabdomyosarcoma cells	Myo D1
	Rhabdomyosarcoma & Ewings tumour cells	Myogenin
	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
	Variable expression dependant on P53 expression, tumour type	P21
	Wild type & mutant P53 protein, seen in range of different lymphoma	P53
	Neural cells, neuroblastoma cells	PGP 9.5
	Prostate glandular tissue, related carcinomas	PSA
	Transcription factor, monocytic lineage, early granulocytes	PU-1
	Neural cells, melanocytes	S100

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, pressure cooker / microwave SOP HP27, HP40, HP42 Using the following monoclonal and polyclonal antibodies:
	Mantle cell lymphoma	SOX-11
	Reed Sternberg/ Hodgkin's cells	TARC
	Normal T & B-lymphocyte precursors. T-ALL & B-ALL cells	TDT
	Lung & thyroid - related tumours	TTF-1
	Molecular genetics examinations for the purpose of haematological malignancy diagnosis and prognosis testing	In house documented methods incorporating manufacturers' instructions where relevant
Paraffin embedded tissue (produced using procedures above or received as a primary sample type), BM smears, PB smears, tissue imprint/Dab, methanol:acetic acid fixed cell suspensions (ammonium chloride lysed BM and PB, CD138+ plasma cell selections	Identification of:	Fluorescent in situ hybridisation: DakoThermoBrite, Stretton ThermoBrite, Vysis HyBrite, Grant HotPlate, Clifton waterbaths, microwave, microfuge, pipettes, Zeiss Fluorescent microscope, MetaSystems FISH workstation using ISIS software Miltenyi Automacs Pro. SOP F001, F002 and FC028 Using the following DNA probes:
	Detect 1p & 1q copy number in myeloma	Cytocell 1p32.2/1q21
	Detect 5q31 copy number in myeloid malignancies	Abbott 5q31/alpha 5
	Detect 7q31 copy number in myeloid malignancies	Abbott 7q31/alpha 7

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Molecular genetics examinations for the purpose of haematological malignancy diagnosis and prognosis testing (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant
Paraffin sections (FFPE), BM smears, PB smears, tissue imprint/Dab, methanol:acetic acid fixed cell suspensions (ammonium chloride lysed BM and PB, CD138+ plasma cell selections	Identification of: (cont'd)	Fluorescent in situ hybridisation: DakoThermoBrite, Stretton ThermoBrite, Vysis HyBrite, Grant HotPlate, Clifton waterbaths, microwave, microfuge, pipettes, Zeiss Fluorescent microscope, MetaSystems FISH workstation using ISIS software Miltenyi Automacs Pro. SOP F001, F002 and FC028 Using the following DNA probes:
	Detect 13q14 copy number in myeloma	Cytocell 13q14/13q34
	Detect 13q14 & chromosome 12 copy number in CLL	Cyocell 13q14 (RB1&DLEU7)/alpha 12
	Detect ATM & TP53 copy number in CLL	Cytocell ATM/TP53
	Detect ATM copy number in CLL	Cytocell ATM/alpha 11
	Detect TP53 copy number in myeloma & B-LBD	Cytocell TP53/alpha 17
	Detect BCL2 gene rearrangement in B-cell LPDs	Dako BCL2
	Detect BCL2-IGH fusion genes in B-cell LPDs	Abbott BCL2/IGH
	Detect BCL6 gene rearrangement in B-cell LPDs	Dako BCL6
	Detect MYC gene rearrangement in B-cell LPDs	Dako MYC
	Detect MALT1 gene rearrangement in B-cell LPDs	Dako MALT1
	Detect MYC gene rearrangement in myeloma & B-cell LPDs	Cytocell MYC

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Molecular genetics examinations for the purpose of haematological malignancy diagnosis and prognosis testing (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant
Paraffin sections (FFPE), BM smears, PB smears, tissue imprint/Dab, methanol:acetic acid fixed cell suspensions (ammonium chloride lysed BM and PB, CD138+ plasma cell selections (cont'd)	Identification of: (cont'd)	Fluorescent in situ hybridisation: DakoThermoBrite, Stretton ThermoBrite, Vysis HyBrite, Grant HotPlate, Clifton waterbaths, microwave, microfuge, pipettes, Zeiss Fluorescent microscope, MetaSystems FISH workstation using ISIS software Miltenyi Automacs Pro. SOP F001, F002 and FC028 Using the following DNA probes:
	Detect MYC-IGH fusion genes in B-cell LPDs	Abbott MYC/IGH/alpha 8
	Detect BCR-ABL fusion genes in CML	Abbott BCR/ABL
	Detect FGFR3-IGH fusion genes in myeloma	Abbott FGFR3/IGH
	Detect FGFR3 gene rearrangement in myeloma	ZytoLight FGFR3 Breakapart
	Detect MAF-IGH fusion genes in B-cell LPDs	Abbott MAF/IGH
	Detect CCND1-IGH fusion genes in B-cell LPDs	Abbott CCND1/IGH/alpha 11
	Detect CCND1 gene rearrangement in B-cell LPDs	Dako CCND1
	Detect CCND1 gene rearrangement in B-cell LPDs	Cytocell CCND1
	Detect CCND2 gene rearrangement in B-cell LPDs	Cytocell CCND2/alpha 12
	Detect IGH gene rearrangement in B-cell LPDs and myeloma	Cytocell IGH
	Detect IGK gene rearrangement in B-cell LPDs	Cytocell IGKappa

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Molecular genetics examinations for the purpose of haematological malignancy diagnosis and prognosis testing (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant
Paraffin sections (FFPE), BM smears, PB smears, tissue imprint/Dab, methanol:acetic acid fixed cell suspensions (ammonium chloride lysed BM and PB, CD138+ plasma cell selections (cont'd)	Identification of: (cont'd)	Fluorescent in situ hybridisation: DakoThermoBrite, Stretton ThermoBrite, Vysis HyBrite, Grant HotPlate, Clifton waterbaths, microwave, microfuge, pipettes, Zeiss Fluorescent microscope, MetaSystems FISH workstation using ISIS software Miltenyi Automacs Pro. SOP F001, F002 and FC028 Using the following DNA probes:
	Detect IGL gene rearrangement in B-cell LPDs	Cytocell IGLambda
	Detect TCL1 gene rearrangement in T-PLL	Cytocell TCL1
	Detect PDGFRA-FIP1L1 fusion genes in eosinophilic & myeloproliferative disorders	Abbott PDGFRA-FIP1L1
	Detect KMT2A gene rearrangement in acute leukaemia	Abbott MLL (KMT2A)
	Detect PML-RARa fusion genes in suspected acute promyelocytic leukaemia (APML) cases	Cytocell PML-RARa (FAST FISH)
	Detect chromosome 8 copy number	Abbott CEP 8
	Detect chromosome 11 copy number	Abbott CEP 11
	Detect chromosome 18 copy number	Abbott CEP18
	Detect DUSP22/IRF4 gene rearrangements in anaplastic large T cell lymphoma and DLBCL	Cytocell DUSP22/IRF4 Breakapart probe
	Detect TP63 gene rearrangements in anaplastic large T cell lymphoma	Cytocell TP63 Breakapart probe

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Molecular genetics examinations for the purpose of haematological malignancy diagnosis and prognosis testing (cont'd) Detect latent EBV infection in various B-cell LPD suspected of being EBV driven (Burkitt's lymphoma, DLBCL, plasmablastic lymphoma, PTLP, Hodgkin lymphoma and infectious mononucleosis)	In house documented methods incorporating manufacturers' instructions where relevant In-situ hybridisation: Dako EBV (EBER) probe (Code Y5200) with Dako PNA ISH Detection Kit (Code K5201), Dako ThermoBrite, Stretton ThermoBrite, Vysis HyBrite, HotPlates, waterbaths, microfuge, pipettes, light microscope. SOP F004

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS (cont'd) Human Nucleic acid obtained from: A. DNA extracted from Blood, bone marrow, fresh tissue & paraffin embedded tissue B. cDNA derived from RNA extracted from Blood, bone marrow & fresh tissue Human Nucleic acid obtained as above from: A. DNA extracted from Blood, bone marrow, fresh tissue & paraffin embedded tissue B. cDNA derived from RNA extracted from Blood, bone marrow & fresh tissue	<u>Molecular genetics examinations for the purpose of haematological malignancy diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant: Manual DNA extraction MH02-04& MH60 & semi automated DNA extraction using Qiagen Qiacubes MH44& 60, water bath, ABI 9700 thermal cycler DNA quantification using Promega Glomax 96 well fluorimeter, microcentrifuge, MH60&62 Sample storage using the FluidX system. MH63&67 Magnetic bead cell fractionation. Dynal magnetic separator, microcentrifuge. MH05. Manual RNA extraction & reverse transcription (to produce cDNA): Micro centrifuge, MJ PTC100 thermal cycler - MJ Research, UV cross-linker. MH06, 23 & 67 Using the following techniques: 1.Agarose gel electrophoresis: Gel former and comb for HE99 gel tank, Consort power supply EV243 (SLS), Oertling digital pan balance HC22 or equivalent, UVP UV transilluminator 312nm, Kodak EDAS 290 digital camera capture system and MI software, Microwave oven.SOP MH08 2. Fluorescent fragment analysis: ABI 3130 Genetic Analyzer, ABI 3500 Genetic Analyzer Eppendorf 5430 centrifuge with a 96 well plate centrifuge head, 1 TB encrypted hard drive (Datalocker) SOP MH11, MH14, MH19, MH49 & MH56

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS (cont'd) Human Nucleic acid obtained as above from: A. DNA extracted from Blood, bone marrow, fresh tissue & paraffin embedded tissue B. cDNA derived from RNA extracted from Blood, bone marrow & fresh tissue	Molecular genetics examinations for the purpose of haematological malignancy diagnosis (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant: 3. Multiplex PCR: ABI 9700 thermal cycler SOP MH14,MH17&MH19 4. ASO PCR: ABI 9700 thermal cycler. SOP MH47, MH57 & MH58 5.Next Generation Sequencing Fluidigm 48:48 access array library preparation & subsequent sequence analysis on the Illumina MiSeq platform. Using: Fluidigm controller units and FC1 thermal cycler, Illumina MiSeq platform, G-Storm thermal cycler, microcentrifuge and eppendorf plate centrifuge. SOP MH78 & MH79. Bioinformatics analysis: SOP BI001, BI003 6. RQ-PCR: Centrifuge with rotor for 96 well optical reaction plates, 7500 Fast Real-Time PCR System (Applied Biosystems). SOP MH35 & MH55 7. Sanger sequencing ABI 9700 thermal cycler & microcentrifuge, ABI 3500 Genetic analyzer. 8. Multiplex Ligation-dependent Probe Amplification (MLPA). Miltenyi Automacs Pro, Qiagen Qiacubes, Promega Glomax 96 well fluorimeter, ABI 9700 thermal cycler, ABI 3130 Genetic Analyzer, ABI 3500 Genetic Analyzer, Coffalyser Analysis Software

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS (cont'd) See above	Molecular genetics examinations for the purpose of haematological malignancy diagnosis (cont'd)	In house documented methods as above incorporating manufacturers' instructions where relevant:
A	T cell clonality testing (diagnostic)	MH14- procedures 2,3
A	B cell clonality testing (diagnostic)	MH19- procedures 2,3
A	t(14;18) detection (diagnostic)	MH17- procedures 1,3
A&B	IGHVH SHM analysis (prognostic)	MH21/22- procedures 1,3,7
B	CML monitoring (therapeutic monitoring)	MH35- procedure 6
A	Chimerism analysis (allogeneic SCT monitoring)	MH36- procedures 2,3
A&B	FLT3 ITD detection (prognostic)	MH34- procedure 2
A&B	NPM1 mutation detection (prognostic)	MH37- procedure 2
B	ABL kinase domain mutational analysis exons 2-10 (prognostic and treatment stratification)	MH38/39/40- procedures 1,7
A	JAK2 exon 12 mutational analysis (diagnostic)	MH41/42- procedures 1,7
A	BRAF V600E mutational analysis (diagnostic & therapeutic stratification)) (diagnostic)	MH45/46- procedures 1,7
A	BRAF V600E mutational analysis (diagnostic & therapeutic stratification))	MH47- procedures 1,4
A	cKIT exon 17 mutational analysis (diagnostic)	MH50/51- procedures 1,7
A	cKIT exon 8 mutational analysis (diagnostic)	MH49- procedure 2
A	CSF3R exon 14 & 17 mutational analysis (diagnostic and therapeutic stratification)	MH53/54- procedures 1,7

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS (cont'd) See above	<u>Molecular genetics examinations for the purpose of haematological malignancy diagnosis</u> (cont'd)	In house documented methods as above incorporating manufacturers' instructions where relevant:
A	STAT3 exon 21 mutational analysis (diagnostic)	MH54/59- procedures 1,7
A	RHOA G17A mutational analysis (diagnostic)	MH58- procedures 1,4
B	Fusion gene detection in acute leukaemia and CML (diagnostic, prognostic and therapeutic stratification)	M55- procedure 6
A	JAK2 V617F & Calreticulin mutational analysis (diagnostic)	MH56- procedures 2,4
A	MYD88 L265P mutational analysis (diagnostic)	MH57- procedures 1,4
B	BCR-ABL1 multiplex analysis (diagnostic)	MH70- procedures 2,3
A	TP53 exons 5-9 mutational analysis (prognostic)	MH71- procedures 1,7
A	CXCR4 mutational analysis (prognostic)	MH72, MH73, MH74 - procedures 1,7
A	MEK1 (MAP2K1) exon 2 & 3 mutational analysis (diagnostic)	MH72, MH73, MH74 - - procedures 1,7
A	Identification of copy number abnormalities in myeloma and CLL	SOP MH81, MH82 – procedures 2, 8 Using MRC Holland kits: SALSA MLPA P425 Multiple Myeloma probemix SALSA MLPA P037 CLL-1 probemix SALSA MLPA EK1 reagent kit – FAM

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS (cont'd) See above	<u>Molecular genetics examinations for the purpose of haematological malignancy diagnosis</u> (cont'd)	In house documented methods as above incorporating manufacturers' instructions where relevant:
A	SRSF2 exon 2 mutational analysis (prognostic) Burkitt mutational panel: CCND3, ID3 & TCF3 (diagnostic & prognostic) CNS/Testis/Leg DLBCL mutational panel: MYD88, CD79B & CARD11 (diagnostic and prognostic). EZH2 mutational analysis (prognostic)	MH72, MH73, MH74- procedures 1,7
A	Detection of gene presence, mutations, deletions;; ASXL1, BCOR, CALR, CBL, CSF3R, DNMT3A, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MPL, NPM1, NRAS, RHOA, RUNX1, SETBP1, SF3B1, SRSF2, STAG2, STAT3, TET2, TP53, U2AF1, U2AF1, WT1 & ZRSR2 (Diagnostic and prognostic)	Targeted amplicon library preparation (Myeloid) using the Fluidigm 48:48 access array. HTS sequence analysis on the Illumina MiSeq MH78. HTS analysis and bioinformatics analysis pipeline MH78, BI001&002-Procedure 5
A	Copy number variation (including CN-LOH)	SNP array analysis: • Illumina® Infinium® HD Assay • Illumina Bead Array Reader and accessory equipment (including Hybridisation ovens, plate vortex, heat blocks and plate sealers) • Te-Flow water circulator & Flow-through Chambers • Refrigerated centrifuge • Vaccum dessiccator • HumanCytoSNP-12 DNA Analysis BeadChip Kit SOPs: MH65, MH66

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	Documented in house methods incorporating manufacturers' instructions where relevant:
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, Mira stainer using May/Grunwald Giemsa Stain Light microscopy SOP GEN001, GEN 004, GEN005 GEN011, GEN016, GEN021
Bone marrow	Bone marrow film - cell typing and morphology	Perls Prussian Blue staining and light microscopy SOP CYT009

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS (cont'd) Blood, bone marrow aspirate CSF, effusions, histological tissue	<u>Haematology examinations for the purpose of haematological malignancy diagnosis</u> (cont'd) Immunophenotyping of the following markers/antigens to diagnose and monitor the following disorders: • Acute Leukaemia - AML, B-ALL and T-ALL. • Chronic Myeloid disorders- MDS, CML, CMML. • Mature Lymphoid Disorders- B & T Lymphoproliferative disorders, Lymphoma and Myeloma. CD CD1a CD2 CD3 CD4 CD5 CD7 CD8 CD9 CD10 CD11c CD13 CD13/33 CD14 CD15 CD16 CD19 CD20 CD22 CD23 CD25 CD26 CD27 CD31 CD33 CD34 CD38 CD39 CD43 CD45 CD49d CD52	Documented in house methods incorporating manufacturers' instructions where relevant: Flow cytometry 8 or 10colour BD Bioscience FACSCanto II flow cytometer using appropriate monoclonal antibody panels SOP FC001 - 3, 022-025, 027, 031, GEN006 SOP FC013-18 SOP FC008 + FC021 SOP FC004-011, FC019, FC026

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS (cont'd) Blood, bone marrow aspirate CSF, effusions, histological tissue (cont'd)	<u>Haematology examinations for the purpose of haematological malignancy diagnosis</u> (cont'd) Immunophenotyping of the following markers/antigens to diagnose and monitor the following disorders (cont'd): • Acute Leukaemia - AML, B-ALL and T-ALL. • Chronic Myeloid disorders- MDS, CML, CMML. • Mature Lymphoid Disorders- B & T Lymphoproliferative disorders, Lymphoma and Myeloma. CD56 CD57 CD58 CD64 CD66c CD79b CD81 CD95 CD103 CD117 CD138 CD185 (CXCR5) CD196 (CCR6) CD200 CD305 HLA-DR IgD IgG IgM Kappa Lambda NG-2 ROR1 TCR	Documented in house methods incorporating manufacturers' instructions where relevant: Flow cytometry 8 or 10colour BD Bioscience FACSCanto II flow cytometer using appropriate monoclonal antibody panels SOP FC001 - 3, 022-025, 027, 031, GEN006 SOP FC013-18 SOP FC008 + FC021 SOP FC004-011, FC019, FC026

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) CD16 CD15 CD14 CD24 CD33 Flaer Alexa-488	Flow cytometry 8 or 10 colour BD Bioscience FACSCanto II flow cytometer using appropriate monoclonal antibody panels SOP FC0020
Blood/Bone Marrow/CSF	Identification of normal or aberrant PML protein expression pattern in suspected cases of Acute Promyelocytic Leukaemia	Immunofluorescence; Zeiss Fluorescent microscope, MetaSystems FISH workstation using ISIS software. SOP IMM006
Histology and haematology slides prepared as above	Morphological assessment and interpretation/diagnosis	Microscopy SOP R1, OFF002
END		