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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 HMDS-HIS-SOP-2, HMDS-HIS-SOP-19 Decalcification HMDS-HIS-SOP-22 Tissue processing/embedding (paraffin): Thermo Scientific Excelsior AS tissue processor & Leica HistoCore Arcadia H embedding centre HMDS-HIS-SOP-3
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 HMDS-HIS-SOP-5, HMDS-HIS-SOP-16

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:
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. HMDS-HIS-SOP-23 Manual Special tinctorial staining: Sakura Prisma Stainer & Film Coverslipper. HMDS-HIS-SOP-23
	Amyloid	Congo Red HMDS-HIS-SOP-13
	Differentiation of different haemopoietic cells	May Grunwald Giemsa HMDS-HIS-SOP-9
	Reticulin fibres	Reticulin (Gordon & Sweets) HMDS-HIS-SOP-8
	Tubercle bacilli	Ziehl-Neelsen HMDS-HIS-SOP-11
	Identification of:	Immunohistochemistry: Dako Autostainers, Dako Omnis, Manual staining HMDS-HIS-SOP-14, HMDS-HIS-SOP-20, HMDS-HIS-SOP-21 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

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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:
	Identification of:	Immunohistochemistry: Dako Autostainers, Dako Omnis, Manual staining HMDS-HIS-SOP-14, HMDS-HIS-SOP-20, HMDS-HIS-SOP-21 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

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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:
	Identification of:	Immunohistochemistry: Dako Autostainers, Dako Omnis, Manual staining HMDS-HIS-SOP-14, HMDS-HIS-SOP-20, HMDS-HIS-SOP-21 Using the following monoclonal and polyclonal antibodies:
	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
	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

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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:
	Identification of:	Immunohistochemistry: Dako Autostainers, Dako Omnis, Manual staining HMDS-HIS-SOP-14, HMDS-HIS-SOP-20, HMDS-HIS-SOP-21 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
	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

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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:
	Identification of:	Immunohistochemistry: Dako Autostainers, Dako Omnis, Manual staining HMDS-HIS-SOP-14, HMDS-HIS-SOP-20, HMDS-HIS-SOP-21 Using the following monoclonal and polyclonal antibodies:
	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
	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

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:
	Identification of:	Immunohistochemistry: Dako Autostainers, Dako Omnis, Manual staining HMDS-HIS-SOP-14, HMDS-HIS-SOP-20, HMDS-HIS-SOP-21 Using the following monoclonal and polyclonal antibodies:
	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)
	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

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:
	Identification of:	Immunohistochemistry: Dako Autostainers, Dako Omnis, Manual staining HMDS-HIS-SOP-14, HMDS-HIS-SOP-20, HMDS-HIS-SOP-21 Using the following monoclonal and polyclonal antibodies:
	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
	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

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:
	Identification of:	Immunohistochemistry: Dako Autostainers, Dako Omnis, Manual staining HMDS-HIS-SOP-14, HMDS-HIS-SOP-20, HMDS-HIS-SOP-21 Using the following monoclonal and polyclonal antibodies:
	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	Genomics analysis for the purpose of clinical diagnosis, prognosis, and patient management 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 **Lineage specific cell separation**
Whole Blood Bone Marrow	Separation of cell fractions CD3, CD15, CD19, CD138	(1) Automated Separation of cell fractions Miltenyi Automacs Pro SOP:HMDS-FLO-SOP-23
Whole Blood Bone Marrow		(2) Manual Separation of lineage specific fractions Dynal Magnetic Separator SOP: HMDS-MOL-SOP-4 **Semi-Automated DNA Extraction**
Whole Blood Bone Marrow Separated cells from blood and bone marrow Fixed Cells Effusions CSF Vitreous biopsies		(3) Qiagen QIAcube with Qiagen QIAamp DNA Blood Mini Kit SOPs: HMDS-MOL-SOP-3 HMDS-MOL-SOP-18
FFPE Tissue Slide Sections Fresh Solid Tissue		(4) Qiagen QIAcube with Qiagen QIAamp DNA FFPE Tissue Kit SOPs: HMDS-MOL-SOP-3 HMDS-MOL-SOP-18

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	In house documented methods incorporating manufacturers' instructions where relevant **DNA Quantification for QC purposes**
Genomic DNA extracted in-house using methods 1 to 4 from the sample types listed or received as primary sample type from an external source		(5) Promega Glomax 96 well fluorimeter SOP: HMDS-MOL-SOP-18
	RNA extraction and preparation of cDNA, for subsequent in-house analysis (see below), referral to specialist centres and long term storage	
		Manual RNA extraction
Whole Blood Bone Marrow Separated Cells from Blood and Bone Marrow		(6) Qiagen RNeasy Mini Kit SOP: HMDS-MOL-SOP-3
		Semi-Automated RNA extraction
Whole Blood Bone Marrow Separated Cells from Blood and Bone Marrow		(7) Promega Maxwell RSC and Maxwell RSC simplyRNA blood kit SOP: HMDS-MOL-SOP-3
		Reverse Transcription
Genomic RNA extracted in-house using methods 6 and 7 from the sample types listed above or received as primary sample type from an external source		(8) Manual method Invitrogen M-MLV reverse transcriptase, Thermal cycler UV cross linker SOP: HMDS-MOL-SOP-3

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS/TISSUE	Genomics analysis for the purpose of clinical diagnosis, prognosis, and patient management	In house documented methods incorporating manufacturers' instructions where relevant **Fragment Analysis**
Genomic DNA extracted in-house using methods 1 to 5 from the sample types listed or received as primary sample type from an external source	Determination of single tandem repeats for Post transplant Chimerism analysis: Loci: Penta E, D18S51, D21S11, TH01, D3S1358, FGA, TPOX, D8S1179, vWA, Amelogenin, Penta D, CSF1PO, D16S539, D7S820, D13S317 and D5S818 Determination of fragment length, known SNVs and indels, gene rearrangements, internal tandem duplications and Single tandem repeats BCR::ABL 1 Multiplex CD15 Chimerism CD3 Chimerism WBC Chimerism FLT3 ITD FLT3 TKD NPM1 IGH DH-JH IGH FR1 IGH FR2 IGH FR3 IGK KDE IGK Vk-Jk TCR Beta TCR gamma	Fluorescent Based Fragment Analysis using commercial methodology and Capillary Electrophoresis Commercial Kits: Powerplex 16 – Chimerism Invivoscribe – TCRB only PCR (including multiplex PCR) using thermal cyclers PCR amplification using verified in-house primer sets from published primers PCR amplification using verified in-house designed primer sets (including TCR) Resolution with Agarose gel electrophoresis and visualisation using UVP UV transilluminator 312nm, Cannon Powershot digital camera capture system and software Bio-Rad GelDoc Go Imaging System Fluorescent fragment analysis ABI 3500/ ABI 3500XL Genetic Analyser Analysis GeneMapper and ChimeRMarker SOPs: HMDS-MOL-SOP-6 HMDS-MOL-SOP-7 HMDS-MOL-SOP-8 HMDS-MOL-SOP-12 HMDS-MOL-SOP-15

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS/TISSUE	Genomics analysis for the purpose of clinical diagnosis, prognosis, and patient management	In house documented methods incorporating manufacturers' instructions where relevant **Qualitative Real Time PCR**
cDNA derived from RNA extracted in house using methods 6 to 8 from the sample types listed or received as primary sample type from an external source	Detection of fusion gene transcripts and determination of breakpoint regions BCR::ABL1 p210 BCR::ABL1 p190 BCR::ABL1 b2a3/b3a3 rare breakpoints CBFB::MYH11 ETV6::RUNX1 PML::RARA RUNX1::RUNX1T1	In house methodology. Real time PCR using Applied Biosystems Realtime 7500 analyser Analysis 7500 analyser software SOPs: HMDS-MOL-SOP-11 HMDS-MOL-SOP-14 HMDS-MOL-SOP-33 HMDS-MOL-SOP-35 **Quantitative Real Time PCR**
cDNA derived from RNA extracted in house using methods 6 to 8 from the sample types listed or received as primary sample type from an external source	Quantification of major breakpoint regions in *BCR-ABL1* fusion transcripts BCR::ABL 1 p210 BCR:: ABL1 p190	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 7500 analyser software SOPs: HMDS-MOL-SOP-11 HMDS-MOL-SOP-14

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS/TISSUE	Genomics analysis for the purpose of clinical diagnosis, prognosis, and patient management	In house documented methods incorporating manufacturers' instructions where relevant **Quantitative Real Time PCR**
cDNA derived from RNA extracted in house using methods 6 to 8 from the sample types listed or received as primary sample type from an external source	Quantification of breakpoint regions of fusion transcripts RUNX1::RUNX1T1 CBFB::MYH11 A	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 7500 Software SOP: HMDS-MOL-SOP-33
cDNA derived from RNA extracted in house using methods 6 to 8 from the sample types listed or received as primary sample type from an external source	Quantification of SNVs and small indels NPM1 A NPM1 B NPM1 D	Real time PCR using ipsogen NPM1 MutaQuant Kits Quantification using Applied Biosystems Realtime 7500 Analysis 7500 software SOPs: HMDS-MOL-SOP-35

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS/TISSUE	Genomics analysis for the purpose of clinical diagnosis, prognosis, and patient management	In house documented methods incorporating manufacturers' instructions where relevant
Genomic DNA extracted in-house using methods 1 to 5 from the sample types listed or received as primary sample type from an external source	Detection of the following SNVs and indels in Somatic myeloid disorders **Pan HaemOnc Gene Panel:** ANKRD26 ARAF ARID1A ASXL1 ATM BCL2 BCOR BIRC3 BRAF BTK CALR CARD11 CBL CCND3 CD79B CDKN1B CEBPA CHEK2 CREBBP CSF3R CUX1 CXCR4 DDX41 DIS3 DNMT3A EP300 ERBB3 ETNK1 ETV6 EZH2 FAM46C FBXW7 FLT3 FOXO1 GATA1 GNB1 HRAS ID3 IDH1	**Next Generation Sequencing** Library Preparation Twist enzymatic fragmentation and Custom Twist probes Thermal cyclers Sequencer NextSeq 550 DX Analysis and interpretation In-house Bioinformatics pipeline (Alignment to genome (GRCh37) with BWA-MEM, small indel variant calling with Mutect2 & Pindel, variant annotation using Alamut Batch) QC, filtering and analysis using in house HaemOncDB v4 SOPs:HMDS-MOL-SOP-34 HMDS-BIO-SOP-7 HMDS-BIO-SOP-8 HMDS-BIO-SOP-9 HMDS-BIO-SOP-12 HMDS-GLH-SOP-1

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS/TISSUE Genomic DNA extracted in-house using methods 1 to 5 from the sample types listed above or received as primary sample type from an external source	Genomics analysis for the purpose of clinical diagnosis, prognosis, and patient management Detection of the following SNVs and indels in Somatic myeloid disorders **Pan HaemOnc Gene Panel:** IDH2 IKZF1 IRF4 JAK2 KIT KLF2 KMT2A KMT2C KRAS MAP2K1 MAP3K1 MEF2B MPL MYD88 NF1 NFE2 NOTCH1 NOTCH2 NPM1 NRAS PIK3CA PIK3CD PLCG2 POT1 PPM1D PTEN PTPN11 RAD21 RHOA RPS15 RUNX1 SETBP1 SF3B1 SH2B3 SRSF2 STAG2 STAT3 STAT5B TCF3	In house documented methods incorporating manufacturers' instructions where relevant **Next Generation Sequencing** Library Preparation Twist enzymatic fragmentation and Custom Twist probes Thermal cyclers Sequencer NextSeq 550 DX Analysis and interpretation In-house Bioinformatics pipeline (Alignment to genome (GRCh37) with BWA MEM, small indel variant calling with Mutect2 & Pindel, variant annotation using Alamut Batch) and HaemOncDB v4 SOPs: HMDS-MOL-SOP-34 HMDS-BIO-SOP-7 HMDS-BIO-SOP-8 HMDS-BIO-SOP-9 HMDS-BIO-SOP-12 HMDS-GLH-SOP-1

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS/TISSUE	Genomics analysis for the purpose of clinical diagnosis of rare disease, inherited and acquired cancer	In house documented methods incorporating manufacturers' instructions where relevant **Next Generation Sequencing**
Genomic DNA extracted in-house using methods 1 to 5 from the sample types listed above or received as primary sample type from an external source	Detection of the following SNVs and indels in Somatic myeloid disorders **Pan HaemOnc Gene Panel:** TET2 TNFAIP3 TP53 U2AF1 UBA1 WT1	Library Preparation Twist enzymatic fragmentation and Custom Twist probes Thermal cyclers Sequencer NextSeq 550 DX Analysis and interpretation In-house Bioinformatics pipeline (Alignment to genome (GRCh37) with BWA MEM, small indel variant calling with Mutect2 & Pindel, variant annotation using Alamut Batch) and HaemOncDB v4 SOPs: HMDS-MOL-SOP-34 HMDS-BIO-SOP-7 HMDS-BIO-SOP-8 HMDS-BIO-SOP-9 HMDS-BIO-SOP-12 HMDS-GLH-SOP-1

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS/TISSUE	Genomics analysis for the purpose of clinical diagnosis of rare disease, inherited and acquired cancer	In house documented methods incorporating manufacturers' instructions where relevant **Next Generation Sequencing**
Genomic DNA extracted using methods 1 to 4 from whole blood and bone marrow or received as primary sample type from an external source	Detection of the following SNVs and indels in Somatic myeloid disorders **MPN BLPD Gene Panel:** CSF3R_Ex14 MPL_Ex10 JAK2_Ex12 JAK2_Ex14 CALR_Ex9	Targeted amplicon library preparation Thermal cyclers Ion GS-S5-PR Sequencer & Ion Chef Analysis and interpretation Analysis steps from base-calling to variant-calling are carried out using ThermoFisher proprietary software on the Torrent Server. Variant annotation using Alamut Batch QC, filtering and analysis using in house HaemOncDB v4 SOPs: HMDS-MOL-SOP-38 HMDS-BIO-SOP-10 HMDS-BIO-SOP-11 HMDS-BIO-SOP-12 HMDS-GLH-SOP-4 **Droplet digital PCR**
Genomic DNA extracted in-house using methods 1 to 5 from the sample types listed or received as primary sample type from an external source	Detection of nucleic acid sequence variants - SNVs and small indels Target detection of: JAK2 V617F c-KIT D816V	BioRad QX200 SOPs: HMDS-MOL-SOP-39 HMDS-MOL-SOP-40

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS/TISSUE	Genomics analysis for the purpose of clinical diagnosis, prognosis, and patient management	In house documented methods incorporating manufacturers' instructions where relevant **Fluorescent in-situ hybridisation (FISH)**
Paraffin embedded tissue Bone marrow smears Peripheral Blood smears Tissue imprint/Dab Methanol : acetic acid fixed cell suspensions Ammonium chloride lysed BM and PB CD19 and CD138 selections from bone marrow aspirate or peripheral blood	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: CytoCell CCND1 Breakapart CytoCell IGH/CCND1 Translocation, Dual Fusion CytoCell CCND2 Breakapart/ 12cen CytoCell ATM/alpha 11 CytoCell TP53/alpha 17 CytoCell BCL2 Breakapart CytoCell BCL6 Breakapart CytoCell MYC Breakapart CytoCell IGH/MYC Translocation, Dual Fusion CytoCell IGK/IGL/MYC Translocation CytoCell 11q23/11q24/11cen CytoCell FIP1L1/ CHIC2/PDGFRA Deletion/Fusion CytoCell IGH/MAFB Translocation, Dual Fusion (MAA preps and bone marrow smears only) CytoCell CBFB breakapart probe CytoCell BCR/ABL(ABL1) Translocation, Dual Fusion CytoCell IGH/MAF Translocation, Dual Fusion CytoCell IGH/FGFR3 Translocation, Dual Fusion CytoCell MLL (KMT2A) Breakapart CytoCell EVI1 (MECOM)	Separation of cell fractions using Miltenyi Automacs Pro Manual FISH performed using commercial probes, CytoBrite Slide Incubation System, MicroFISH Hybridization Oven, Clifton waterbaths, microwave, pressure cooker, microfuge and pipettes. Analysis Cytovision analysis software and and Leica fluorescent microscope system SOPs: HMDS-FIS-SOP-2 HMDS-FIS-SOP-3 HMDS-FIS-SOP-5 HMDS-FLO-SOP-23

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS/TISSUE	Genomics analysis for the purpose of clinical diagnosis of rare disease, inherited and acquired cancer	In house documented methods incorporating manufacturers' instructions where relevant **Fluorescent in-situ hybridisation (FISH)**
Paraffin embedded tissue Bone marrow smears Peripheral Blood smears Tissue imprint/Dab Methanol : acetic acid fixed cell suspensions Ammonium chloride lysed BM and PB CD19 & CD138 selections from bone marrow aspirate or peripheral blood,	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: CytoCell PDGFRB Breakapart CytoCell ABL1 Breakapart probe CytoCell ABL2 Breakapart probe CytoCell E2A/PBX1 Plus Translocation, dual fusion CytoCell E2A Breakapart CytoCell TEL/AML1 (ETV6/RUNX1) Translocation,Dual Fusion CytoCell TCL1 Breakapart CytoCell FAST PML/RARα (RARA) Translocation, Dual Fusion CytoCell IGH Breakapart CytoCell CRLF2 breakaprt probe CytoCell RUNX1/RUNX1T1 dual-fusion translocation probe	Separation of cell fractions using Miltenyi Automacs Pro Manual FISH performed using commercial probes, CytoBrite Slide Incubation System, MicroFISH Hybridization Oven, Clifton waterbaths, microwave, pressure cooker, microfuge and pipettes. Analysis Cytovision analysis software and and Leica fluorescent microscope system SOPs: HMDS-FIS-SOP-2 HMDS-FIS-SOP-3 HMDS-FIS-SOP-5 HMDS-FLO-SOP-23

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS/TISSUE	Genomics analysis for the purpose of clinical diagnosis of rare disease, inherited and acquired cancer	In house documented methods incorporating manufacturers' instructions where relevant **Fluorescent in-situ hybridisation (FISH)**
Paraffin embedded tissue	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: Agilent MYC Agilent BCL2 Agilent BCL6 Agilent MYC/IGH Agilent DUSP22/IRF4 breakapart probe Agilent TP63 breakapart probe Agilent CCND2 breakapart probe Agilent CCND1 breakapart probe Agilent MALT1 breakapart probe Agilent MYC/K & MYC/L dual-fusion translocation probes	Automated FISH performed using Dako OMNIS automated platform using commercial probes. Analysis Cytovision analysis software and and Leica fluorescent microscope system SOPs: HMDS-FIS-SOP-2 HMDS-FIS-SOP-3 HMDS-FIS-SOP-5 HMDS-FLO-SOP-23
		SNP Array
SNP array data files received from an external source	Detection of DNA copy number variation and loss of heterozygosity.	Analysis and interpretation of SNP array data using BlueFuse Multi and web-based UCSC genome browser. SOP: HMDS-MOL-SOP-20

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. HMDS-REC-SOP-10
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 HMDS-REC-SOP-1 HMDS-REC-SOP-2 HMDS-REC-SOP-3 HMDS-REC-SOP-6 HMDS-GEN-SOP-1 HMDS-REC-SOP-7

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, 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 HMDS-FLO-SOP-2 HMDS-FLO-SOP-4 HMDS-FLO-SOP-17 HMDS-FLO-SOP-22 HMDS-REC-SOP-4 HMDS-FLO-SOP-5 HMDS-FLO-SOP-12 HMDS-FLO-SOP-21
	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	Haematology examinations for the purpose of haematological malignancy diagnosis	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 HMDS-FLO-SOP-2 HMDS-FLO-SOP-4 HMDS-FLO-SOP-17 HMDS-FLO-SOP-20 HMDS-FLO-SOP-22 HMDS-REC-SOP-4 HMDS-FLO-SOP-5 HMDS-FLO-SOP-12 HMDS-FLO-SOP-21
	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	Haematology examinations for the purpose of haematological malignancy diagnosis	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 HMDS-FLO-SOP-17 HMDS-FLO-SOP-20 HMDS-FLO-SOP-22 HMDS-REC-SOP-4 HMDS-FLO-SOP-13

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, 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 HMDS-FLO-SOP-17 HMDS-FLO-SOP-20 HMDS-FLO-SOP-22 HMDS-REC-SOP-4 HMDS-FLO-SOP-14
	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	Haematology examinations for the purpose of haematological malignancy diagnosis	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 HMDS-FLO-SOP-17 HMDS-FLO-SOP-20 HMDS-FLO-SOP-22 HMDS-REC-SOP-4 HMDS-FLO-SOP-14
	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	6 colours

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, 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 HMDS-FLO-SOP-2 HMDS-FLO-SOP-4 HMDS-FLO-SOP-17 HMDS-FLO-SOP-20 HMDS-FLO-SOP-22 HMDS-REC-SOP-4 HMDS-FLO-SOP-12 HMDS-FLO-SOP-15
	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	Haematology examinations for the purpose of haematological malignancy diagnosis	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 HMDS-FLO-SOP-2 HMDS-FLO-SOP-4 HMDS-FLO-SOP-17 HMDS-FLO-SOP-20 HMDS-FLO-SOP-22 HMDS-REC-SOP-4 HMDS-FLO-SOP-12 HMDS-FLO-SOP-15
	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	Haematology examinations for the purpose of haematological malignancy diagnosis	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)Red blood cells:	Flow cytometry performed on Becton Dickinson Facs Lyric instrument using defined monoclonal antibody panels HMDS-FLO-SOP-16 HMDS-FLO-SOP-25
	Red blood cells: CD235a CD59 CD71 CD3d Leucocytes: CD16 CD15 CD14 CD24 CD33 Flaer Alexa-488 CD157	4 Colours 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 HMDS-FLO-SOP-28
Histology and haematology slides prepared as above	Morphological assessment and interpretation/diagnosis	Microscopy HMDS-REP-SOP-1, HMDS-OFF-SOP-3
END		