


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>UKAS</b> MEDICAL 9305</p> <p>Accredited to ISO 15189:2012</p>	<h3>Leeds Teaching Hospitals NHS Trust</h3> <p>Issue No: 007    Issue date: 17 May 2022</p>	
	<p><b>Haematological Malignancy Diagnostic Service</b> St. James' University Hospital Leeds LS9 7TF United Kingdom</p>	<p><b>Contact: Dr Catherine Cargo / Dr Ruth De Tute</b> Tel: +44 (0)1132067963 Fax: +44 (0)1132067883 E-Mail: <a href="mailto:catherine.cargo@nhs.net">catherine.cargo@nhs.net</a> / <a href="mailto:rdetute@nhs.net">rdetute@nhs.net</a> Website: <a href="http://www.hmnds.info">www.hmnds.info</a></p>
<p><b>Testing performed at the above address only</b></p>		

### DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY TISSUE AND FLUIDS</p> <p>Tissue</p> <p>Tissue within paraffin blocks (produced using procedures above or received as a primary sample type)</p>	<p><u>Histopathology examination activities in order to identify or exclude morphological abnormalities for the purpose of haematological malignancy diagnosis</u></p>	<p>Macroscopic and Microscopic examination:</p> <p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Tissue dissection: Morphology SOP HP01, HP39</p> <p>Decalcification SOP HP44</p> <p>Tissue processing/embedding (paraffin): Thermo Scientific Excelsior AS tissue processor &amp; Leica HistoCore Arcadia H embedding centre SOP HP04</p> <p>Microtomy (paraffin blocks): Microm HM325 &amp; Leica HistoCore Autocut microtomes, water baths, hot-plates SOP HP06, HP32</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Paraffin (produced using procedures above or received as a primary sample type) embedded tissue</p>	<p><u>Histopathology examination activities in order to identify or exclude morphological abnormalities for the purpose of haematological malignancy diagnosis (cont'd)</u></p> <p>Identification of:</p> <p>Basophilic and eosinophilic structures</p> <p>Amyloid</p> <p>Differentiation of different haemopoietic cells</p> <p>Glycogen (and other PAS positive substances)</p> <p>Heamosiderin</p> <p>Reticulin fibres</p> <p>Tubercle bacilli</p> <p>Identification of:</p> <p>T-cells, mantle zone B-cells , follicular lymphomas</p> <p>Germinal centre B-cells &amp; related lymphomas</p> <p>Activated B-cells, plasma cells</p>	<p>Macroscopic and Microscopic examination:</p> <p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Automated Haematoxylin &amp; Eosin and May Grunwald Giemsa staining using Leica ST5020, light microscope SOP HP11, SOP HP13</p> <p>Manual Special tinctorial staining: Microm coverslipper, light microscope SOP HP12, HP14, HP15, HP19, HP21</p> <p>Congo Red (HP21)</p> <p>May Grunwald Giemsa (HP13)</p> <p>PAS (+/- diastase) (HP19)</p> <p>Perls' (HP14)</p> <p>Reticulin (Gordon &amp; Sweets) (HP12)</p> <p>Ziehl-Neelsen (HP15)</p> <p>Immunohistochemistry: Dako Autostainers, Dako Omnis, Manual staining SOP HP27, HP40, HP42 Using the following monoclonal and polyclonal antibodies:</p> <p>Bcl-2 (clones 124 &amp; E17)</p> <p>Bcl-6</p> <p>Blimp-1</p>



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



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<p><u>Histopathology examination activities in order to identify or exclude morphological abnormalities for the purpose of haematological malignancy diagnosis (cont'd)</u></p> <p>Identification of: (cont'd)</p> <p>B-cells &amp; associated B-Cell lymphomas, normal plasma cells</p> <p>B-cells &amp; associated B-Cell lymphomas</p> <p>Follicular dendritic cells, mature B-cells</p> <p>B-cells, associated B-cell lymphomas</p> <p>Follicular dendritic cells, B-cells, CLL cells</p> <p>Activated T-cells, inter-leukin-2 receptor cells</p> <p>Activated B &amp; T-cells, Reed Sternberg / Hodgkin's cells</p> <p>Endothelial cells, blast cells</p> <p>Pan Leucocyte marker- normal &amp; neoplastic cells</p> <p>NK cells, nerve cells, neuroblastomas, some neoplastic PCs</p> <p>NK cells, related lymphomas</p>	<p>Macroscopic and Microscopic examination:</p> <p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Immunohistochemistry: Dako Autostainers, Dako Omnis, Manual staining SOP HP27, HP40, HP42 Using the following monoclonal and polyclonal antibodies:</p> <p>CD19</p> <p>CD20</p> <p>CD21</p> <p>CD22</p> <p>CD23</p> <p>CD25</p> <p>CD30</p> <p>CD34</p> <p>CD45</p> <p>CD56</p> <p>CD57</p>



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<p><u>Histopathology examination activities in order to identify or exclude morphological abnormalities for the purpose of haematological malignancy diagnosis (cont'd)</u></p> <p>Identification of: (cont'd)</p> <p>Megakaryocytes, megakaryocytes precursors, and platelets</p> <p>Macrophages &amp; myeloid cells</p> <p>B-cells &amp; associated B-Cell lymphomas</p> <p>Ewings sarcoma, lymphocytes</p> <p>Melanocytes, mast cells, AML tumour cells, GIST</p> <p>Kikuchi disease</p> <p>Normal &amp; neoplastic plasma cells, epithelial cells</p> <p>Assist in identification of positive cells in myeloid sarcomas and T-ALL</p> <p>Macrophages, monocytes</p> <p>Alk + tumours (ALCL)</p> <p>Plasma cells, plasmacytic lymphoma vs myeloma</p> <p>Normal &amp; neoplastic epithelial cells (intestinal)</p> <p>Identification of myeloid sarcomas and T-ALL</p> <p>Normal &amp; neoplastic epithelia (breast)</p>	<p>Macroscopic and Microscopic examination:</p> <p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Immunohistochemistry: Dako Autostainers, Dako Omnis, Manual staining SOP HP27, HP40, HP42 Using the following monoclonal and polyclonal antibodies:</p> <p>CD61</p> <p>CD68</p> <p>CD79a</p> <p>CD99</p> <p>CD117 C-KIT</p> <p>CD123</p> <p>CD138</p> <p>CD13</p> <p>CD163</p> <p>CD246</p> <p>CD319 (manual staining only)</p> <p>CDX2</p> <p>CD33</p> <p>CK 7</p>



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<p><u>Histopathology examination activities in order to identify or exclude morphological abnormalities for the purpose of haematological malignancy diagnosis (cont'd)</u></p> <p>Identification of: (cont'd)</p> <p>Normal &amp; neoplastic epithelia (colon)</p> <p>Cells showing Myc translocation, disease related</p> <p>Epithelial cells, Mantle cell lymphoma</p> <p>Broad spectrum of normal &amp; neoplastic epithelia</p> <p>Broad spectrum of normal &amp; neoplastic epithelia</p> <p>Follicular helper T-cells, angioblastic T-cell lymphomas</p> <p>Suggestive of Hairy Cell Leukaemia</p> <p>Smooth &amp; striated muscle</p> <p>Endothelial cells, Megakaryocytes</p> <p>Erythroid cells &amp; precursors</p> <p>Cytotoxic T-cells &amp; NK cells &amp; related lymphomas</p> <p>HLA class II DR antigen expressing cells</p>	<p>Macroscopic and Microscopic examination:</p> <p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Immunohistochemistry: Dako Autostainers, Dako Omnis, Manual staining SOP HP27, HP40, HP42 Using the following monoclonal and polyclonal antibodies:</p> <p>CK20</p> <p>C Myc</p> <p>Cyclin D1</p> <p>Cytokeratin - Cam 5.2</p> <p>Cytokeratin - MNF116</p> <p>CXCL13</p> <p>Leukaemia Hairy cell (DBA44)</p> <p>Desmin</p> <p>Factor VIII</p> <p>Glycophorin C</p> <p>Granzyme B</p> <p>HLA-DR</p>



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<p><u>Histopathology examination activities in order to identify or exclude morphological abnormalities for the purpose of haematological malignancy diagnosis (cont'd)</u></p> <p>Identification of: (cont'd)</p> <p>Karposi sarcoma virus, associated multicentric Castleman's disease</p> <p>IgA expressing plasma cells</p> <p>IgD expressing plasma cells, Mantle zone B-cells</p> <p>IgG expressing plasma cells &amp; lymphocytes</p> <p>Specific subtype of plasma cells, IgG4 disease</p> <p>IgM expressing plasma cells, mantle zone B-cells</p> <p>Plasma cells, activated T-cells, some germinal centre B-cells, R/S cells &amp; associated lymphomas</p> <p>Kappa light chain expressing plasma cells and lymphoid cells (mantle zone B-cells)</p> <p>Lambda light chain expressing plasma cells and lymphoid cells (mantle zone B-cells)</p> <p>Langerhan's cells, IRDC's</p> <p>Diagnosis of follicular lymphoma</p>	<p>Macroscopic and Microscopic examination:</p> <p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Immunohistochemistry: Dako Autostainers, Dako Omnis, Manual staining SOP HP27, HP40, HP42 Using the following monoclonal and polyclonal antibodies:</p> <p>HHV8</p> <p>IgA (manual staining only)</p> <p>IgD</p> <p>IgG (manual staining only)</p> <p>IgG4 (manual staining only)</p> <p>IgM (manual staining only)</p> <p>IRF4</p> <p>Kappa (manual staining only)</p> <p>Lambda (manual staining only)</p> <p>Langerin</p> <p>LMO2</p>



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<p><u>Histopathology examination activities in order to identify or exclude morphological abnormalities for the purpose of haematological malignancy diagnosis (cont'd)</u></p> <p>Identification of: (cont'd)</p> <p>EBV</p> <p>Histiocytes</p> <p>Mast cells, related disorders</p> <p>Melanoma cells</p> <p>Proliferating cells</p> <p>Myeloid cells</p> <p>Rhabdomyosarcoma cells</p> <p>Rhabdomyosarcoma &amp; Ewings tumour cells</p> <p>B-cells, Germinal centre cells, plasma cells</p> <p>Embryonic cells &amp; germ cells &amp; related diseases</p> <p>B-cells</p> <p>Follicular Helper T-cells</p>	<p>Macroscopic and Microscopic examination:</p> <p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Immunohistochemistry: Dako Autostainers, Dako Omnis, Manual staining SOP HP27, HP40, HP42 Using the following monoclonal and polyclonal antibodies:</p> <p>LMP-1</p> <p>Lysozyme</p> <p>Mast-cell tryptase</p> <p>Melanoma monoclonal</p> <p>MIB1</p> <p>Myeloperoxidase</p> <p>Myo D1</p> <p>Myogenin</p> <p>OCT-2</p> <p>OCT-3/4</p> <p>PAX-5</p> <p>PD1</p>





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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<p><u>Histopathology examination activities in order to identify or exclude morphological abnormalities for the purpose of haematological malignancy diagnosis (cont'd)</u></p> <p>Identification of: (cont'd)</p> <p>Neural cells, neuroblastoma cells</p> <p>Prostate glandular tissue, related carcinomas</p> <p>Transcription factor, monocytic lineage, early granulocytes</p> <p>Neural cells, melanocytes</p> <p>Mantle cell lymphoma</p> <p>Normal T &amp; B-lymphocyte precursors. T-ALL &amp; B-ALL cells</p>	<p>Macroscopic and Microscopic examination:</p> <p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Immunohistochemistry: Dako Autostainers, Dako Omnis, Manual staining SOP HP27, HP40, HP42 Using the following monoclonal and polyclonal antibodies:</p> <p>PGP 9.5</p> <p>PSMA</p> <p>PU-1</p> <p>S100</p> <p>SOX-11</p> <p>TDT</p>



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<p>HUMAN BODY FLUIDS/TISSUE</p> <p>Whole Blood Bone Marrow</p> <p>Whole Blood Bone Marrow</p> <p>Whole Blood Bone Marrow Separated cells from blood and bone marrow Fixed Cells Effusions CSF Vitreous biopsies</p>	<p>Genomics analysis for the purpose of clinical diagnosis, prognosis, and patient management</p> <p>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</p>	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p>Manual and Automated separation of cell fractions</p> <p><b>Automated</b> Separation of cell fractions:  Using  Miltenyi Automacs Pro SOP FC028</p> <p><b>Manual</b> Separation of lineage specific fractions  Using:  Dynal Magnetic Separator  SOP MH05</p> <p>Manual and semi-automated and automated DNA extraction and quantification using:</p> <p><b>Semi-Automated Extraction</b> Qiagen QIAcube with Qiagen QIAamp DNA Blood Mini Kit  SOP MH02 SOP MH62</p>



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



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HUMAN BODY FLUIDS/TISSUE  Genomic DNA extracted in-house 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 (cont'd)  Detection of nucleic acid sequence variants - SNVs and small indels  [Definitive list HMDS4406]	In house documented methods incorporating manufacturers' instructions where relevant  <b>Reverse Transcription</b>  Manual method  using  Invitrogen M-MLV reverse transcriptase, thermal cycler and UV cross linker  SOP MH02  <b>Sanger Sequencing</b>  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



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



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HUMAN BODY FLUIDS/TISSUE	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



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<p>HUMAN BODY FLUIDS/TISSUE</p> <p>Genomic DNA extracted in-house from the sample types listed above or received as primary sample type from an external source</p>	<p>Genomics analysis for the purpose of clinical diagnosis, prognosis, and patient management (cont'd)</p> <p>Detection of whole exon deletions/duplications</p> <p>[Definitive list HMDS4408]</p>	<p><b>In house documented methods incorporating manufacturers' instructions where relevant</b></p> <p><b>Fragment Analysis for Multiplex Ligation-dependent Probe Amplification (MLPA)</b></p> <p>Multiplex Ligation Probe Analysis (MLPA) using: Commercial commercial MRC Holland kits and Thermal cyclers and ABI 3500 Genetic Analyzer</p> <p>Analysis using Coffalyser Analysis Software</p> <p>SOPs MH81 MH82</p>



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<p>HUMAN BODY FLUIDS/TISSUE</p> <p>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</p> <p>cDNA received as primary sample type or derived from RNA extracted and reverse transcribed in-house from blood and bone marrow</p>	<p>Genomics analysis for the purpose of clinical diagnosis, prognosis, and patient management (cont'd)</p> <p>Detection of fusion gene transcripts and determination of breakpoint regions</p> <p>[Definitive list HMDS4409]</p> <p>Quantification of major breakpoint regions in <i>BCR-ABL1</i> fusion transcripts</p> <p>[Definitive list: HMDS4409]</p>	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p><b>Qualitative Real Time PCR</b> In house methodology.</p> <p>Real time PCR using Applied Biosystems Realtime 7500 analyser</p> <p>Analysis using 7500 analyser software</p> <p>SOPs</p> <p>MH35 MH55</p> <p><b>Quantitative Real Time PCR</b> In house real time PCR methodology with EAC primers and probes.</p> <p>Ipsogen Qiagen plasmids standard curve used for quantitative assay</p> <p>Quantification using Applied Biosystems Realtime 7500 analyser</p> <p>Analysis using 7500 analyser software</p> <p>SOPs</p> <p>MH35 MH55</p>





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



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<p>HUMAN BODY FLUIDS/TISSUE</p> <p>Genomic DNA extracted in-house from the sample types listed above or received as primary sample type from an external source</p> <p>Genomic DNA extracted in-house from the sample types listed above or received as primary sample type from an external source</p>	<p>Genomics analysis for the purpose of clinical diagnosis, prognosis, and patient management (cont'd)</p> <p>Screening of large targeted single or multigene panels for genetic variants</p> <p>[Definitive list HMDS4410]</p> <p>SNVs and small indels</p> <p>Screening of large targeted single or multigene panels for genetic variants</p> <p>[Definitive list HMDS4410]</p> <p>SNVs and small indels</p>	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p><b>Next Generation Sequencing</b></p> <p>Targeted amplicon library preparation</p> <p>Fluidigm 48:48 access array with High Throughput Sequencing</p> <p>Using</p> <p>Thermal cyclers and Illumina MiSeq</p> <p>Analysis using in-house Bioinformatics pipeline</p> <p>SOPs</p> <p>MH78 MH83 BI001 BI002 BI003 BI004</p> <p>Library Preparation using Twist enzymatic fragmentation and Custom Twist probes</p> <p>Using</p> <p>Thernak cyclers and NextSeq 550 DX</p> <p>Analysis and interpretation using in-house Bioinformatics pipeline and HaemOncDB v 3 respectively</p> <p>SOPs:</p> <p>MH87 BI010 BI011 BI012 YNEGLH004 YNEGLH002</p>



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<p>HUMAN BODY FLUIDS/TISSUE</p> <p>Paraffin embedded tissue Bone marrow smears Peripheral Blood smears Tissue imprint/Dab Methanol:acetic acid fixed cell suspensions Ammonium chloride lysed BM and PB CD138+ plasma cell selections</p>	<p>Genomics analysis for the purpose of clinical diagnosis, prognosis, and patient management (cont'd)</p> <p>Detection and analysis of genomic rearrangements and imbalances in:</p> <p>Haemato-Oncological disorders Bone Marrow failure Identification/Confirmation of genomic rearrangements, gains and losses – using</p> <p>Locus specific probes:</p> <p>Break apart Dual colour dual fusion Copy Number/Amplification</p> <p>[Definitive list of probes HMDS4504]</p>	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p><b>Fluorescent in-situ hybridisation (FISH)</b></p> <p>Separation of cell fractions using Miltenyi Automacs Pro</p> <p>FISH performed using commercial probes, CytoBrite Slide Incubation System, MicroFISH Hybridization Oven Grant HotPlate, Clifton waterbaths, microwave, pressure cooker, microfuge and pipettes.</p> <p>Analysis using: Cytovision analysis software and and Leica fluorescent microscope system</p> <p>SOPs</p> <p>F001 F002 FC028</p>
<p>FFPE</p>	<p>Detection of EBV infection in B-Cell lymphoproliferative disorders</p>	<p><b>In-situ hybridisation</b></p> <p>ISH performed using Dako EBV (EBER) probe (with Dako PNA ISH Detection Kit</p> <p>CytoBrite Slide Incubation System, MicroFISH Hybridization Oven Grant HotPlate, Clifton waterbaths, microwave, microfuge and pipettes.</p> <p>Analysis using Light Microscopy</p> <p>SOP</p> <p>F004</p>



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HUMAN BODY FLUIDS/TISSUE	Genomics analysis for the purpose of clinical diagnosis, prognosis, and patient management (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant
SNP array data files received from an external source within the YNEGLH	Detection of DNA copy number variation and loss of heterozygosity.	<b><u>SNP Array – Data analysis only:</u></b> Analysis and interpretation of SNP array data using BlueFuse Multi and web-based UCSC genome browser.  SOP MH66
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	Morphological assessment of haematopoietic cells	Automated May Grunwald Giemsa staining using Leica ST5020 Light microscopy SOP GEN004
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



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Blood, bone marrow aspirate CSF, effusions, histological tissue</p>	<p><u>Haematology examinations for the purpose of haematological malignancy diagnosis (cont'd)</u></p> <p>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- &amp; T- lymphoproliferative disorders Myeloma/MGUS</p> <p>Stem Cell Screen (SCS): CD64 CD45 CD38 CD10 CD19 CD117 CD34 HLA-DR</p> <p>B-cell screen (BLS): CD19 CD20 CD5 CD10 CD305 (LAIR-1) CD45 Kappa Lambda</p> <p>T-cell screen (TLS): CD3 CD4 CD8 CD16/CD56 CD45 CD7 CD5 HLA-DR</p>	<p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Flow cytometry on Becton Dickinson FACS Canto II using defined monoclonal antibody panels SOP FC001 - 003, FC022-025, FC027, GEN006 SOP FC004-011, FC026</p> <p>8 colours</p> <p>8 colours</p> <p>8 colours</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Blood, bone marrow aspirate CSF, effusions, histological tissue</p>	<p><u>Haematology examinations for the purpose of haematological malignancy diagnosis (cont'd)</u></p> <p>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- &amp; T- lymphoproliferative disorders Myeloma/MGUS (cont'd)</p> <p>Plasma cell screen: CD38 CD138 CD19 CD45 CD56 CD117 CD27 CD81</p> <p>Outreach monitoring (CMP): CD19 CD38 CD45 CD5 Kappa Lambda</p> <p>Rituximab monitoring: CD3 CD14 CD19 CD38 CD27 CD45</p>	<p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Flow cytometry on Becton Dickinson FACS Canto II using defined monoclonal antibody panels SOP FC001 - 003, FC022-025, FC027, GEN006 SOP FC004-011, FC026</p> <p>8 colours</p> <p>6 colours</p> <p>6 colours</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Blood, bone marrow aspirate CSF, effusions, histological tissue</p>	<p><u>Haematology examinations for the purpose of haematological malignancy diagnosis (cont'd)</u></p> <p>Immunophenotyping of the following markers/antigens in an 8-colour panel to diagnose and monitor myeloid disorders (AML, MDS, CMML)</p> <p>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</p>	<p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Flow cytometry performed on Becton Dickinson Facs Lyric instrument using defined monoclonal antibody panels SOP FC022-025 &amp; 027, GEN006 SOP FC013</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Blood, bone marrow aspirate CSF, effusions, histological tissue (cont'd)</p>	<p><u>Haematology examinations for the purpose of haematological malignancy diagnosis (cont'd)</u></p> <p>Immunophenotyping of the following markers/antigens to diagnose and monitor Acute lymphoblastic leukaemia (B-ALL &amp; T-ALL)</p> <p>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</p>	<p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Flow cytometry performed on Facs Lyric instrument using defined monoclonal antibody panels SOP FC022-025, 027, GEN006 SOP FC015 &amp; FC017 8 colours</p>





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



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Blood, bone marrow aspirate CSF, effusions, histological tissue</p>	<p><u>Haematology examinations for the purpose of haematological malignancy diagnosis (cont'd)</u></p> <p>Immunophenotyping of the following markers/antigens to diagnose and monitor mature B- and T-cell lymphoproliferative disorders:</p> <p>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</p>	<p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Flow cytometry on Becton Dickinson FACS Canto II using defined monoclonal antibody panels SOP FC001 - 003, FC022-025, FC027, GEN006 FC011, FC019</p> <p>8 colours</p>



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



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Haematology examinations for the purpose of haematological malignancy diagnosis (cont'd)</u>	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 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 SOP IMM006
Histology and haematology slides prepared as above	Morphological assessment and interpretation/diagnosis	Microscopy SOP R1, OFF002
END		