


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p>Accredited to ISO 15189:2012</p>	<h3>Leeds Teaching Hospitals NHS Trust</h3> <p>Issue No: 004    Issue date: 26 May 2020</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.hmds.info">www.hmds.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>Bone marrow trephine biopsies within resin blocks (produced historically in house using accredited procedure)</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 HP01</p> <p>Tissue processing/embedding (paraffin): Thermo Shandon Excelsior ES tissue processor &amp; Thermo Shandon embedding centre SOP HP04</p> <p>Microtomy (paraffin blocks): Microm microtomes, water baths, hot-plates SOP HP06, HP32</p> <p>Microtomy (resin blocks): Riechert Autocut microtomes, Leica Glass knife maker SOP HP07</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) and resin (produced using procedures above) 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>Nuclei and other cellular components and tissue structures</p> <p>Identification of:</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>Manual Haematoxylin and Eosin staining: Microm coverslipper, light microscope SOP HP11</p> <p>Manual Special tinctorial staining: Microm coverslipper, light microscope SOP HP12, HP13, 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, pressure cooker / microwave 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</u> (cont'd)</p> <p>Identification of: (cont'd)</p> <p>B-cells, Germinal centre cells, plasma cells</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, pressure cooker / microwave SOP HP27, HP40, HP42 Using the following monoclonal and polyclonal antibodies:</p> <p>BOB-1</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</u> (cont'd)</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>Plasma 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, pressure cooker / microwave 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>CD38</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</u> (cont'd)</p> <p>Identification of: (cont'd)</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, pressure cooker / microwave SOP HP27, HP40, HP42 Using the following monoclonal and polyclonal antibodies:</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</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</u> (cont'd)</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>Post germinal centre B-cells</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, pressure cooker / microwave 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>FOXP1</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</u> (cont'd)</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, pressure cooker / microwave SOP HP27, HP40, HP42 Using the following monoclonal and polyclonal antibodies:</p> <p>HHV8</p> <p>IgA</p> <p>IgD</p> <p>IgG</p> <p>IgG4</p> <p>IgM</p> <p>IRF4</p> <p>Kappa</p> <p>Lambda</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</u> (cont'd)</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>Variable expression dependant on P53 expression, tumour type</p> <p>Wild type &amp; mutant P53 protein, seen in range of different 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, pressure cooker / microwave 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> <p>P21</p> <p>P53</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</u> (cont'd)</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>Reed Sternberg/ Hodgkin's cells</p> <p>Normal T &amp; B-lymphocyte precursors. T-ALL &amp; B-ALL cells</p> <p>Lung &amp; thyroid - related tumours</p>	<p>Macroscopic and Microscopic examination:</p> <p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Immunohistochemistry: Dako Autostainers, Dako Omnis, pressure cooker / microwave SOP HP27, HP40, HP42 Using the following monoclonal and polyclonal antibodies:</p> <p>PGP 9.5</p> <p>PSA</p> <p>PU-1</p> <p>S100</p> <p>SOX-11</p> <p>TARC</p> <p>TDT</p> <p>TTF-1</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>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)</p>	<p><u>Molecular genetics examinations for the purpose of haematological malignancy diagnosis and prognosis testing</u></p> <p>Identification of:</p> <p>Detect 1p &amp; 1q copy number in myeloma</p> <p>Detect 5q31 copy number in myeloid malignancies</p> <p>Detect 7q31 copy number in myeloid malignancies</p> <p>Detect 13q14 copy number in myeloma</p> <p>Detect 13q14 &amp; chromosome 12 copy number in CLL</p> <p>Detect ATM &amp; TP53 copy number in CLL</p> <p>Detect ATM copy number in CLL</p> <p>Detect TP53 copy number in myeloma &amp; B-LBD</p> <p>Detect BCL2 gene rearrangement in B-cell LPDs</p> <p>Detect BCL2-IGH fusion genes in B-cell LPDs</p> <p>Detect BCL6 gene rearrangement in B-cell LPDs</p>	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p>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:</p> <p>Cytocell 1p32.2/1q21</p> <p>Abbott 5q31/alpha 5</p> <p>Abbott 7q31/alpha 7</p> <p>Cytocell 13q14/13q34</p> <p>Cyocell 13q14 (RB1&amp;DLEU7)/alpha 12</p> <p>Cytocell ATM/TP53</p> <p>Cytocell ATM/alpha 11</p> <p>Cytocell TP53/alpha 17</p> <p>Dako BCL2</p> <p>Abbott BCL2/IGH</p> <p>Dako BCL6</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>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)</p>	<p><u>Molecular genetics examinations for the purpose of haematological malignancy diagnosis and prognosis testing (cont'd)</u></p> <p>Identification of: (cont'd)</p> <p>Detect MYC gene rearrangement in B-cell LPDs</p> <p>Detect MALT1 gene rearrangement in B-cell LPDs</p> <p>Detect MYC gene rearrangement in myeloma &amp; B-cell LPDs</p> <p>Detect MYC-IGH fusion genes in B-cell LPDs</p> <p>Detect BCR-ABL fusion genes in CML</p> <p>Detect FGFR3-IGH fusion genes in myeloma</p> <p>Detect FGFR3 gene rearrangement in myeloma</p> <p>Detect MAF-IGH fusion genes in B-cell LPDs</p> <p>Detect CCND1-IGH fusion genes in B-cell LPDs</p> <p>Detect CCND1 gene rearrangement in B-cell LPDs</p>	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p>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:</p> <p>Dako MYC</p> <p>Dako MALT1</p> <p>Cytocell MYC</p> <p>Cytocell MYC/IGH/alpha 8</p> <p>Cytocell BCR/ABL</p> <p>Cytocell FGFR3/IGH</p> <p>ZytoLight FGFR3 Breakapart</p> <p>Abbott MAF/IGH</p> <p>Cytocell CCND1/IGH/alpha 11</p> <p>Dako CCND1</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>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)</p>	<p><u>Molecular genetics examinations for the purpose of haematological malignancy diagnosis and prognosis testing (cont'd)</u></p>	<p>In house documented methods incorporating manufacturers' instructions where relevant</p>
	<p>Identification of: (cont'd)</p>	<p>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:</p>
	<p>Detect CCND1 gene rearrangement in B-cell LPDs</p>	<p>CytoCell CCND1</p>
	<p>Detect CCND2 gene rearrangement in B-cell LPDs</p>	<p>CytoCell CCND2/alpha 12</p>
	<p>Detect IGH gene rearrangement in B-cell LPDs and myeloma</p>	<p>CytoCell IGH</p>
	<p>Detect IGK gene rearrangement in B-cell LPDs</p>	<p>CytoCell IGKappa</p>
	<p>Detect IGL gene rearrangement in B-cell LPDs</p>	<p>CytoCell IGLambda</p>
	<p>Detect TCL1 gene rearrangement in T-PLL</p>	<p>CytoCell TCL1</p>
	<p>Detect PDGFRA-FIP1L1 fusion genes in eosinophilic &amp; myeloproliferative disorders</p>	<p>Abbott PDGFRA-FIP1L1</p>
	<p>Detect KMT2A gene rearrangement in acute leukaemia</p>	<p>CytoCell MLL (KMT2A)</p>
<p>Detect PML-RARa fusion genes in suspected acute promyelocytic leukaemia (APML) cases</p>	<p>CytoCell PML-RARa (FAST FISH)</p>	
<p>Detect chromosome 8 copy number</p>	<p>Abbott CEP 8</p>	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Molecular genetics examinations for the purpose of haematological malignancy diagnosis and prognosis testing (cont'd)</u>	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 chromosome 11 copy number	Cytocell CEP 11
	Detect chromosome 18 copy number	Cytocell 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
	Detect 11q gain/loss	Cytocell 11q gain/loss FISH probe
	Detect EVI1 (MECOM) breakapart	Cytocell EVI1 (MECOM) breakapart FISH probe
	Detect ABL1 rearrangements in ALL	Cytocell ABL1 dual colour, breakapart probe
	Detect ABL2 rearrangements in ALL	Cytocell ABL2 dual colour, breakapart probe
	Detect E2A/PBX1 rearrangements in ALL	Cytocell E2A/PBX1 Plus Translocation, dual fusion probe
	Detect E2A rearrangements in ALL	Cytocell E2A breakapart probe
	Detect TEL/AML1 (ETV6/RUNX1) rearrangements in ALL	Cytocell TEL/AML1 (ETV6/RUNX1) Translocation, Dual Fusion



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>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)</p>	<p><u>Molecular genetics examinations for the purpose of haematological malignancy diagnosis and prognosis testing (cont'd)</u></p> <p>Identification of: (cont'd)</p> <p>Detect PDGFRB rearrangements in eosinophilia patients</p> <p>Detect FGFR1 rearrangements in eosinophilia patients</p> <p>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)</p>	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p>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:</p> <p>Cytocell PDGFRB breakapart probe</p> <p>Cytocell FGFR1 breakapart probe</p> <p>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</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Blood, bone marrow, fresh tissue &amp; paraffin embedded tissue</p>	<p><u>Molecular genetics examinations for the purpose of haematological malignancy diagnosis and prognosis testing (cont'd)</u></p>	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p>Manual DNA extraction MH02 &amp; semi automated DNA extraction using Qiagen Qiacubes, water bath</p> <p>DNA quantification using Promega Glomax 96 well fluorimeter, microcentrifuge, MH62</p> <p>Automated RNA extraction using Maxwell RSC instrument. Promega Maxwell RSC simply RNA cells kit. MH02</p> <p>Sample storage using the FluidX system. MH63</p> <p>Magnetic bead cell fractionation. Dynal magnetic separator, microcentrifuge. MH05.</p> <p>Manual RNA extraction &amp; reverse transcription (to produce cDNA): Micro centrifuge, MJ PTC100 thermal cycler - MJ Research, UV cross-linker. MH02 &amp; 67</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Human Nucleic acid obtained as above from:</p> <p>A. DNA extracted from Blood, bone marrow, fresh tissue &amp; paraffin embedded tissue</p> <p>B. cDNA derived from RNA extracted from Blood, bone marrow &amp; fresh tissue</p>	<p><u>Molecular genetics examinations for the purpose of haematological malignancy diagnosis</u></p>	<p>In house documented methods incorporating manufacturers' instructions where relevant:</p> <p>Using the following techniques:</p> <p>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</p> <p>2. Fluorescent fragment analysis: ABI 3500 Genetic Analyzer Eppendorf 5430 centrifuge with a 96 well plate centrifuge head, 1 TB encrypted hard drive (Datalocker) SOP MH11, MH14, MH19 &amp; MH56</p> <p>3. Multiplex PCR: Techne Prime, Biorad T100 thermal cyclers SOP MH14 &amp; MH19</p> <p>4. ASO PCR: Techne Prime, Biorad T100 thermal cyclers. SOP MH47, MH57 &amp; MH58</p> <p>5. Next Generation Sequencing Fluidigm 48:48 access array library preparation &amp; 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 . Bioinformatics analysis: SOP BI001, BI003</p> <p>6. RQ-PCR: Centrifuge with rotor for 96 well optical reaction plates, 7500 Fast Real-Time PCR System (Applied Biosystems). SOP MH35 &amp; MH55</p>





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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Human Nucleic acid obtained as above from:</p> <p>A. DNA extracted from Blood, bone marrow, fresh tissue &amp; paraffin embedded tissue</p> <p>B. cDNA derived from RNA extracted from Blood, bone marrow &amp; fresh tissue</p>	<p><u>Molecular genetics examinations for the purpose of haematological malignancy diagnosis (cont'd)</u></p>	<p>In house documented methods incorporating manufacturers' instructions where relevant:</p> <p>7. Sanger sequencing Biorad T100, G-Storm thermal cyclers &amp; microcentrifuge, ABI 3500 Genetic analyzer.</p> <p>8. Multiplex Ligation-dependent Probe Amplification (MLPA). Miltenyi Automacs Pro, Qiagen Qiacubes, Promega Glomax 96 well fluorimeter, Biorad T100 thermal cycler, ABI 3500 Genetic Analyzer, Coffalyser Analysis Software</p>



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<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:
See above		
A	T cell clonality testing (diagnostic)	MH14- procedures 2,3
A	B cell clonality testing (diagnostic)	MH19- procedures 2,3
A&B	IGHVH SHM analysis (prognostic)	MH21- 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)	MH34- procedure 2
B	ABL kinase domain mutational analysis exons 2-10 (prognostic and treatment stratification)	MH38- procedures 1,7
A	JAK2 exon 12 mutational analysis (diagnostic)	MH72/73- procedures 1,7
A	BRAF V600E mutational analysis (diagnostic & therapeutic stratification)	MH47- procedures 1,4,7
A	cKIT exon 17 mutational analysis (diagnostic)	MH72/73- procedures 1,7
A	cKIT exon 8 mutational analysis (diagnostic)	MH788- procedure 2
A	CSF3R exon 14 & 17 mutational analysis (diagnostic and therapeutic stratification)	MH72/73- procedures 1,7



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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)	MH55- 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	CEBPA 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



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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 & BI004- Procedure 5
A	HTS panel for the diagnosis and prognosis of CLL & MZL genes presence, mutations, insertions and deletions: ARID1A, ATM, BRAF, BRIC3, BTK, CARD11, CCND1, CD79B, CDKN1B, CREBBP, CXCR4, EGR2, EP300, FBXW7, KLF2, MAP2K1, MED12, MYD88, NFKBIE, NOTCH1, NOTCH2, PLCG2, POT1, RPS15, SF3B1, TLR2, TNFAIP3, TP53, TRAF2, TRAF3, UBR5, WHSC1 & XPO1	Targeted amplicon library preparation (Lymphoid) using the Fluidigm 48:48 access array. HTS sequence analysis on the Illumina MiSeq MH83 HTS analysis and bioinformatics analysis pipeline BI001, 2 & 4-Procedure 5



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>See above</p> <p>A</p>	<p><u>Molecular genetics examinations for the purpose of haematological malignancy diagnosis (cont'd)</u></p> <p>Copy number variation (including CN-LOH)</p>	<p>In house documented methods as above incorporating manufacturers' instructions where relevant:</p> <p>SNP array analysis:</p> <ul style="list-style-type: none"> <li>• Illumina® Infinium® HD Assay</li> <li>• Illumina Bead Array Reader and accessory equipment (including Hybridisation ovens, plate vortex, heat blocks and plate sealers)</li> <li>• Te-Flow water circulator &amp; Flow-through Chambers</li> <li>• Refrigerated centrifuge</li> <li>• Vacuum dessiccator</li> <li>• HumanCytoSNP-12 DNA Analysis BeadChip Kit</li> </ul> <p>SOPs: MH65, MH66</p>



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Haematology examinations for the purpose of haematological malignancy diagnosis</u>	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



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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 the following disorders:</p> <ul style="list-style-type: none"> <li>Acute Leukaemia - AML, B-ALL and T-ALL.</li> <li>Chronic Myeloid disorders- MDS, CML, CMML.</li> <li>Mature Lymphoid Disorders- B &amp; T Lymphoproliferative disorders, Lymphoma and Myeloma.</li> </ul> <p>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</p>	<p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Flow cytometry 8 or 10colour BD Bioscience FACSCanto II flow cytometer using appropriate monoclonal antibody panels</p> <p>SOP FC001 - 3, 022-025, 027, 031, GEN006 SOP FC013-18 SOP FC008 + FC021 SOP FC004-011, FC019, FC026</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 the following disorders (cont'd):</p> <ul style="list-style-type: none"> <li>Acute Leukaemia - AML, B-ALL and T-ALL.</li> <li>Chronic Myeloid disorders- MDS, CML, CMML.</li> <li>Mature Lymphoid Disorders- B &amp; T Lymphoproliferative disorders, Lymphoma and Myeloma.</li> </ul> <p>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</p>	<p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Flow cytometry 8 or 10colour BD Bioscience FACSCanto II flow cytometer using appropriate monoclonal antibody panels</p> <p>SOP FC001 - 3, 022-025, 027, 031, GEN006 SOP FC013-18 SOP FC008 + FC021 SOP FC004-011, FC019, FC026</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)  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		