


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 9615</p> <p>Accredited to ISO 15189:2022</p>	<p>Imperial College Healthcare NHS Trust operating as North West London Pathology</p> <p>Issue No: 014 Issue date: 09 February 2026</p>	
	<p>Charing Cross Hospital Rm 2L20, Pathology Quality Office Fulham Palace Road London W6 8RF</p>	<p>Contact: Helen Hobson Tel: +44 (0) 20 8321 6153 E-Mail: helen.hobson1@nhs.net Website: www.NWLPathology.nhs.uk</p>
<p>Testing performed by the Organisation at the locations specified below</p>		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details		Activity	Location code
Address	Local contact		
Charing Cross Hospital Fulham Palace Road Hammersmith London W6 8RF	Tyrone Dickson	Histopathology Electron Microscopy Diagnostic Cytology	X-Histo X-EM
Hammersmith Hospital Du Cane Road East Acton London W12 0HS	Tyrone Dickson	Frozen section histology Molecular Diagnostics/MRD Immunophenotyping Cytogenetics	H-Histo H-MOL H-Immunop H-CytoG

Site activities performed away from the locations listed above:

Location details		Activity	Location code
MOHS Chelsea and Westminster		MOHS, frozen section histology	C-MOHS
Endobronchial ultrasound (EBUS) Clinic	SMH	FNA material/slide preparation & cellularity assessment	M-FNA



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
<p>HUMAN BODY TISSUE AND FLUIDS</p> <p>Tissues: biopsy, excision and resection.</p>	<p><u>Histopathological examinations for the purpose of clinical diagnosis</u></p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p>	<p>In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:</p> <p><u>Tissue dissection:</u></p> <p>Amputation - CELP-CP-013-NWL</p> <p>Bladder - CELP-CP-019-NWL</p> <p>Breast - CELP-CP-011-NWL</p> <p>Central and peripheral nervous system tumours - CELP-CP-040-NWL</p> <p>Head & Neck - CELP-CP-009-NWL</p> <p>Kidney - CELP-CP-020-NWL</p> <p>Osteoarticular - CELP-CP-014-NWL</p> <p>Penis - CELP-CP-021-NWL</p> <p>Prostate - CELP-CP-000-NWL</p> <p>Salivary gland - CELP-ED-278-NWL</p> <p>Skin - CELP-CP-008-NWL</p> <p>Testis - CELP-CP-023-NWL</p> <p>Gynaecological SOP - CELP-CP-015-NWL</p> <p>Respiratory Specimens cut-up SOP - CELP-CP-037-NWL</p>	<p>X-Histo</p> <p>X-Histo</p> <p>X-Histo</p> <p>X-Histo</p> <p>X-Histo</p> <p>X-Histo</p> <p>X-Histo</p> <p>X-Histo</p> <p>X-Histo</p> <p>X-Histo</p> <p>X-Histo</p> <p>X-Histo</p> <p>X-Histo</p> <p>X-Histo</p> <p>X-Histo</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Tissues: biopsy, excision and resection (cont'd)</p>	<p><u>Histopathological examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</p>	<p>In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:</p> <p>Haematopathology cut-up SOP - CELP-CP-024-NWL</p> <p>Hepatopancreaticobiliary SOP - CELP-CP-026-NWL</p> <p>Kidney Transplant Resection - CELP-CP-027-NWL</p> <p>Pancreas Transplant Resection - CELP-CP-028-NWL</p> <p>Thyroid and Parathyroid - CELP-CP-029-NWL</p> <p>Temporal Artery Samples - CELP-CP-030-NWL</p> <p>Upper G.I Cancer -CELP-CP-003-NWL</p> <p>Colorectal Specimens - CELP-CP-004-NWL</p> <p>Liver SOP - CELP-CP-005-NWL</p> <p>Placenta SOP - CELP-CP-006-NWL</p> <p>Bowel Cancer Screening Programme (BCSP) Specimen Handling - CELP-CP-032-NWL</p> <p>Gallbladder and Appendices – CELP-CP-033-NWL</p> <p>Specimen transfer SOP CELP-LP-046-NWL</p>	<p>X-Histo</p> <p>X-Histo</p> <p>X-Histo</p> <p>X-Histo</p> <p>X-Histo</p> <p>X-Histo</p> <p>X-Histo</p> <p>X-Histo</p> <p>X-Histo</p> <p>X-Histo</p> <p>X-Histo</p> <p>X-Histo</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Tissues: biopsy, excision and resection (cont'd)</p> <p>Fresh tissue</p>	<p><u>Histopathological examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p>	<p>In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:</p> <p><u>Decalcification:</u></p> <p>Decalcification - CELP-LP-035-NWL</p> <p><u>Frozen sections:</u></p> <p>Leica cryostat CM1950 Preparing Tissue for Frozen Section, Cryotomy and Diagnosis - CELP-LP-048-NWL</p> <p>Thermo Cryostar NX50 Preparing Tissue for Frozen Section, Cryotomy and Diagnosis - CELP-LP-206-NWL</p> <p>Technical Processing of MOHS in support of Histological Examination Leica cryostat CM1950 CELP-LP-086-NWL</p>	<p>X-Histo</p> <p>H-Histo</p> <p>X-Histo</p> <p>C-MOHS</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Formalin fixed tissue processed to paraffin wax (FFPE), Fresh tissue, Frozen Tissue, Cell blocks</p>	<p><u>Histopathological examinations for the purpose of clinical diagnosis (cont'd)</u></p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p>	<p>In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:</p>	
		<p><u>Tissue processing</u> - Leica Peloris 3 CELP-LP-199-NWL</p>	X-Histo
		<p><u>Embedding</u> -: HistoCore Arcadia</p>	
		<p>Embedding Protocol - CELP-LP-192-NWL</p>	X-Histo
		<p><u>Microtomy</u> - Leica RM2255 Leica HistoCore Autocut microtome</p>	
		<p>Microtomy Procedure - CELP-LP-197-NWL</p>	X-Histo
		<p><u>Automated staining and coverslipping</u> - Leica ST5020 (autostainer), Leica CV5030 (coverslipper); <u>Autostainer and Coverslipper (CELP-LP-207-NWL)</u></p>	
		<p><u>Automated routine staining</u> - Ventana HE 600</p>	
		<p>Ventana HE 600 System - CELP-LP-205-NWL</p>	X-Histo



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections.</p>	<p><u>Histopathological examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Special staining of Histopathology examinations to assist in detection of clinical abnormalities:</p> <p>Acid mucins</p> <p>Acid and neutral mucins</p> <p>Collagen/mallory bodies/giant mitochondria</p> <p>Elastic fibres & connective tissue</p> <p>Haematopoietic cells</p> <p>Gram +/- organisms</p> <p>Fibrin/connective tissue/muscle</p> <p>Argentaffin/melanin</p> <p>Helicobacter Pylori</p>	<p>In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:</p> <p><u>Automated routine staining</u> - Thermo Scientific Linistat Linear Stainer:</p> <p>Mohs - CELP-LP-172-C</p> <p><u>Manual techniques:</u></p> <p>Alcian Blue - CELP-LP-172-NWL</p> <p>Alcian Blue Diastase Periodic Acid Schiff - CELP-LP-081-NWL</p> <p>Chromotrope Aniline Blue Stain - CELP-LP-008-NWL</p> <p>Elastic Picro Sirius - CELP-LP-068-NWL</p> <p>Giemsa Stain CELP-LP-070-NWL</p> <p>Gram Stain - CELP-LP-009-NWL</p> <p>Haematoxylin Van Gieson Stain - CELP-LP-012-NWL</p> <p>Masson Fontana Stain – CELP-LP-029-NWL</p> <p>Modified Giemsa Stain - CELP-LP-121-NWL</p>	<p>C-MOHS</p> <p>X-Histo</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections. Fresh tissue.</p>	<p><u>Histopathological examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Special staining of Histopathology examinations to assist in detection of clinical abnormalities (cont'd)</p> <p>Neutral mucins/polysaccharides/fungi/basement membranes/glycogen</p> <p>Haemosiderin/Iron</p> <p>Mast cell granules</p> <p>Calcium salts</p> <p><i>Mycobacterium leprae</i></p> <p><i>Mycobacterium spp.</i> including tuberculosis</p>	<p>In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:</p> <p><u>Manual techniques (cont'd):</u></p> <p>Periodic Acid Schiff +/- Diastase Stain - CELP-LP-067-NWL</p> <p>Perls Stain - CELP-LP-005-NWL</p> <p>Toluidine Blue - CELP-LP-073-NWL</p> <p>Von Kossa - CEPL-LP-034-NWL</p> <p>Wade Fite - CELP-LP-033-NWL</p> <p>Ziehl Neelson - CELP-LP-074-NWL</p>	<p>X-Histo</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections (cont'd).</p>	<p><u>Histopathological examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p>	<p>In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:</p> <p>Sakura Tissue-Tek Film Automated Coverslipper. SOP: use and maintenance of Sakura Automated Coverlipping Machine - CELP-LP-016-NWL</p> <p>Automated special staining – Dako Artisan Link Pro - Artisan Staining System SOP, CELP-LP-209-NWL:</p>	X-Histo
			<p>Amyloid</p> <p>Basement Membranes</p> <p>Fungi</p> <p>Fibrin / Connective Tissue / Muscle</p> <p>Hepatitis B surface antigen/copper associated protein.</p> <p>Reticulin Fibres</p> <p>Spirochetes / Helicobacter</p>



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological examinations for the purpose of clinical diagnosis</u> (cont'd)		
In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections (cont'd).	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	Manual Direct Skin Immunofluorescence: CEL-LP-298-NWL - IF: Receipt, freezing and Slides preparation and CELP-LP-055-NWL - Immunofluorescence Staining Using antibodies for:	X-Histo
Skin frozen sections	Bullous diseases, pemphigoid, LE - C3c complement	C3c	X-Histo
	Bullous diseases, pemphigoid, LE - Fibrinogen	Fibrinogen	X-Histo
	Bullous diseases, pemphigoid, LE - IgA alpha chain	IgA	X-Histo
	Bullous diseases, pemphigoid, LE - IgG gamma chain	IgG	X-Histo
	Bullous diseases, pemphigoid, LE - IgM mu chain	IgM	X-Histo



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological examinations for the purpose of clinical diagnosis</u> (cont'd)		
In house preparations of frozen tissue sections	Identification of antigens at a subcellular level by means of fluorescent antibodies	<u>Manual immunofluorescence:</u>	
	C1q complement	C1q	X-Histo
	C3c complement	C3c	
	IgA alpha chain	IgA	
	IgG gamma chain	IgG	
	IgM mu chain	IgM	
	Light chain deposition	Kappa	
	Light chain deposition	Lambda	
		<u>Automated immunocytochemistry - Bond III:</u>	X-Histo
		Automated Immunocytochemistry for the Bond - CELP-LP-056-NWL	
		Using antibodies for:	
	Fetal liver cells, liver disease	a-fetoprotein	
	Anaplastic large cell lymphoma	ALK-1	



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	AA-amyloidosis	Amyloid A	
	Androgen receptor	Androgen receptor	
	Mantle cell lymphoma	bcl-1/Cyclin D1	
	B and T cells in the mantle and marginal zone	bcl-2	
	B and T cells in the mantle and marginal zone	bcl-2 alt	
	Nuclei of germinal B cells	bcl-6	
	Epithelial cells	BerEP4	
	Epithelial cells and fibroblasts	beta-Catenin	
	B cells	BOB-1	
	Complement activation	C5b9	
	Peritubular and glomerular capillaries	C4d	
	Renal cell carcinomas	CA-IX	



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections (cont'd)</p>	<p><u>Histopathological examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</p> <p>Luminal surface of epithelial cells of the fallopian tube, endometrium and endocervix.</p> <p>Tumour cells in GI and pancreas carcinomas</p> <p>C-cells</p> <p>Smooth muscle</p> <p>Mesothelial cells</p> <p>Epithelial cells (low molecular weight)</p> <p>Pre B and T cells, some T cells, germinal centre cells</p>	<p>In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:</p> <p><u>Automated immunocytochemistry - Bond III:</u></p> <p>Automated Immunocytochemistry for the Bond - CELP-LP-056-NWL</p> <p>Using antibodies for:</p> <p>CA-125</p> <p>Ca19.9</p> <p>Calcitonin</p> <p>H-Caldesmon</p> <p>Calretinin</p> <p>Cam5.2</p> <p>CD10</p>	<p>X-Histo</p>



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	<p>Follicular dendritic and mature B cells</p>	<p>CD21</p>	
	<p>B cells and EBV transformed B lymphoblasts</p>	<p>CD23</p>	
	<p>Marker for hairy cell leukemia and systemic mastocytosis</p>	<p>CD25</p>	
	<p>Pan T cells</p>	<p>CD3</p>	
	<p>Reed-Sternburg cells</p>	<p>CD30</p>	
	<p>Endothelial cells</p>	<p>CD31</p>	
	<p>Myelomonocytic lineage cells</p>	<p>CD33</p>	
	<p>Endothelial cells</p>	<p>CD34</p>	
	<p>Immature T and B cells, thymocytes, plasma cells</p>	<p>CD38</p>	



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections (cont'd)</p>	<p><u>Histopathological examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</p> <p>Cytotoxic T cells</p> <p>Intestinal epithelium</p> <p>Neuroendocrine cells</p> <p>Mast cells and GIST</p> <p>Overexpression in hematopoietic tumours</p> <p>Epithelial cells</p> <p>High molecular weight cytokeratin - basal cells</p> <p>Basal cells of squamous and glandular epithelium</p> <p>Epithelial cells</p> <p>Basal cells of squamous and some glandular epithelium</p> <p>Basal cells of complex epithelia</p>	<p>In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:</p> <p><u>Automated immunocytochemistry - Bond III:</u></p> <p>Automated Immunocytochemistry for the Bond - CELP-LP-056-NWL</p> <p>Using antibodies for:</p> <p>CD8</p> <p>CDX2</p> <p>Chromogranin A</p> <p>C-kit CD117</p> <p>C-Myc</p> <p>Cytokeratin AE1/AE3</p> <p>Cytokeratin 34BE12</p> <p>Cytokeratin 5</p> <p>Cytokeratin 8/18</p> <p>Cytokeratin 14</p> <p>Cytokeratin 17</p>	<p>X-Histo</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections (cont'd)</p>	<p><u>Histopathological examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</p> <p>Simple epithelium</p> <p>Epithelial cells</p> <p>Gastric and intestinal epithelium, urothelium and Merkel cells</p> <p>Glandular and transitional epithelium</p> <p>Epithelial cells</p> <p>Cytomegalovirus</p> <p>Lymphatic endothelium</p> <p>Hairy cell Leukaemia</p> <p>Smooth, skeletal and cardiac muscle</p> <p>GIST</p> <p>Latent EBV RNA within B cells</p>	<p>In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:</p> <p><u>Automated immunocytochemistry - Bond III:</u></p> <p>Automated Immunocytochemistry for the Bond - CELP-LP-056-NWL</p> <p>Using antibodies for:</p> <p>Cytokeratin 18</p> <p>Cytokeratin 19</p> <p>Cytokeratin 20</p> <p>Cytokeratin 7</p> <p>Cytokeratin MNF116</p> <p>Cytomegalovirus</p> <p>D2-40</p> <p>DBA 44</p> <p>Desmin</p> <p>DOG-1</p> <p>EBER ISH</p>	<p>X-Histo</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections (cont'd).</p>	<p><u>Histopathological examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</p>	<p>In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:</p> <p><u>Automated immunocytochemistry - Bond III:</u></p> <p>Automated Immunocytochemistry for the Bond - CELP-LP-056-NWL</p> <p>Using antibodies for:</p>	<p>X-Histo</p>
	Epithelial tissue	E-cadherin	
	Epithelial cells	EMA	
	Dermatofibroma	Factor XIIIa	
	T cells	Fox P3	
	Gastrin producing cells in the stomach	Gastrin	
	Bladder carcinoma	Gata-3	
	Apocrine epithelia of skin and breast	GCDFP-15 (BRST2)	
	Astrocytes, Schwann cells, glial cells, satellite cells	GFAP (GA5)	
	Glucagon secreting cells	Glucagon	
	Cytotoxic T cells and NK cells	Granzyme B	
	K light chain mRNA	Kappa (ISH)	



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections (cont'd)</p>	<p><u>Histopathological examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</p> <p>Helicobacter pylori in stomach</p> <p>Trophoblasts</p> <p>Adult and fetal liver</p> <p>HSV I</p> <p>HSV II</p> <p>Latent nuclear antigen protein</p> <p>Antigen presenting cells, B cells and some activated T cells</p> <p>Surface IgA alpha - Myeloma</p> <p>Surface IgD delta chains</p> <p>Surface IgG gamma</p>	<p>In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:</p> <p><u>Automated immunocytochemistry - Bond III:</u></p> <p>Automated Immunocytochemistry for the Bond - CELP-LP-056-NWL</p> <p>Using antibodies for:</p> <p>H. pylori</p> <p>HCG</p> <p>Hepatocyte/HepPar1</p> <p>Herpes simplex I</p> <p>Herpes simplex II</p> <p>HHV8</p> <p>HLA-DR</p> <p>IgA (BMT)</p> <p>IgD</p> <p>IgG (BMT)</p>	<p>X-Histo</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections (cont'd)</p>	<p><u>Histopathological examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</p>	<p>In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:</p> <p><u>Automated immunocytochemistry - , Bond III:</u></p> <p>Automated Immunocytochemistry for the Bond - CELP-LP-056-NWL</p> <p>Using antibodies for:</p>	X-Histo
	IgG4 positive plasma cells	IgG4	
	Surface IgM mu chains	IgM (BMT)	
	Ovarian granulosa cells, testicular sertoli and leydig cells	Inhibin	
	Beta cells of the islets of Langerans in pancreas	Insulin	
	Surface immunoglobulin on B cells	Kappa (Lymphoma)	
	Proliferating cells	Ki67 (K2)	
	Lambda light chain mRNA	Lambda (ISH)	
	Surface immunoglobulin on B cells	Lambda (Lymphoma)	
	Langerhans cells	Langerin	
	Pre B and T cells	Lef-1	



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections (cont'd)</p>	<p><u>Histopathological examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</p> <p>Detects circulating / met breast cancer cells</p> <p>Mast cells</p> <p>Melanocytes, junctional and blue nevus cells</p> <p>Melanocytes/ melanomas</p> <p>Some lymphocytes, cortical thymocytes, granulosa cells of the ovary, Langerhans islet cells, sertoli cells</p> <p>Apical surfaces of epithelial cells in breast, GI, respiratory and GU tracts</p> <p>Goblet cells of the small intestine and colon, bronchus and salivary glands</p>	<p>In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:</p> <p><u>Automated immunocytochemistry - , Bond III:</u></p> <p>Automated Immunocytochemistry for the Bond - CELP-LP-056-NWL</p> <p>Using antibodies for:</p> <p>Mammaglobin</p> <p>Mast Cell Tryptase</p> <p>Mel Sp Ag (HMB45)</p> <p>Melan A</p> <p>Mic-2</p> <p>MUC-1</p> <p>MUC-2</p>	<p>X-Histo</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections (cont'd)</p>	<p><u>Histopathological examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</p> <p>Gastric and tracheo-bronchial mucosa, primary ovarian mucinous carcinoma</p> <p>Antrum body and pyloric glands</p> <p>Germinal centre B cells, plasma cells and activated T cells</p> <p>Precursors of granulocytes in BMT</p> <p>Skeletal and cardiac muscle</p> <p>Rhabdomyosarcoma</p> <p>Type II pneumocytes and lung adenocarcinoma</p> <p>Neurones, Neuronal processes, peripheral nerves and ganglion cells</p>	<p>In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:</p> <p><u>Automated immunocytochemistry - Bond III:</u></p> <p>Automated Immunocytochemistry for the Bond - CELP-LP-056-NWL</p> <p>Using antibodies for:</p> <p>MUC-5AC</p> <p>MUC-6</p> <p>MUM1</p> <p>Myeloperoxidase</p> <p>Myoglobin</p> <p>Myo D1</p> <p>Napsin A</p> <p>Neurofilaments</p>	<p>X-Histo</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections (cont'd)</p>	<p><u>Histopathological examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</p>	<p>In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:</p> <p><u>Automated immunocytochemistry - Bond III:</u></p> <p>Automated Immunocytochemistry for the Bond - CELP-LP-056-NWL</p> <p>Using antibodies for:</p>	X-Histo
	Neuroendocrine cells	NSE	
	B cells	OCT-2	
	Embryonic stem and germ cells	OCT 3/4	
	HPV	P16 (RTU)	
	P40 protein in squamous cell carcinomas	p40	
	Tumour suppressor protein	P53 (D07)	
	Basal cells	P63	
	Prostate adenocarcinoma	P504S (AMACR)	
	Chief cells in the parathyroid gland	Parathyroid hormone	
	B cells	Pax-5	
	Thyroid, renal cell carcinomas	Pax-8	



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections (cont'd)</p>	<p><u>Histopathological examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</p> <p>Activated T cells, B cells and myeloid cells</p> <p>Cytotoxic T cells and NK cells</p> <p>Megakaryocytes</p> <p>Neuroendocrine cells</p> <p>Syncytiotrophoblasts</p> <p>Germ cell tumours</p> <p>Glandular epithelium in prostate</p> <p>Glandular epithelium in prostate</p> <p>Tumour suppressor protein</p> <p>Red cells and their precursors</p>	<p>In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:</p> <p><u>Automated immunocytochemistry - , Bond III:</u></p> <p>Automated Immunocytochemistry for the Bond - CELP-LP-056-NWL</p> <p>Using antibodies for:</p> <p>PD1</p> <p>Perforin</p> <p>PGP3 (CD61)</p> <p>PGP9.5</p> <p>Plac. Lactogen (PL)</p> <p>PLAP</p> <p>Pros acid phos (PAP)</p> <p>Prostate specific antigen (PSA)</p> <p>PTEN</p> <p>Ret40f/Glycophorin C</p>	<p>X-Histo</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections (cont'd)</p>	<p><u>Histopathological examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</p> <p>Melanocytes, Langerhans cells, histiocytes, Schwann cells, apidocytes</p> <p>Enterochromaffin cells of the GI tract</p> <p>Smooth muscle cells, myofibroblasts and myoepithelial cells</p> <p>Pancreatic islets, delta cells in the antrum and duodenum</p> <p>Mantle cell lymphoma</p> <p>SV-40</p> <p>Neuroendocrine cells</p> <p>T cells</p> <p>Primitive T and B cells, thymocytes</p> <p>Thyroid follicular cells</p>	<p>In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:</p> <p><u>Automated immunocytochemistry - , Bond III:</u></p> <p>Automated Immunocytochemistry for the Bond - CELP-LP-056-NWL</p> <p>Using antibodies for:</p> <p>S-100</p> <p>Serotonin</p> <p>Smooth Muscle Actin</p> <p>Somatostatin</p> <p>SOX-11</p> <p>SV-40 (Bk virus)</p> <p>Synaptophysin</p> <p>TCR-Beta F1</p> <p>Tdt</p> <p>Thyroglobulin</p>	<p>X-Histo</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections (cont'd)</p>	<p><u>Histopathological examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</p> <p>Treponema Pallidum</p> <p>Follicular epithelial cells of the thyroid, type II pneumocytes and Clara cells of the lung</p> <p>Hairy cell Leukaemia</p> <p>Fibroblasts, endothelial cells, smooth muscle and melanocytes</p>	<p>In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:</p> <p><u>Automated immunocytochemistry - , Bond III:</u></p> <p>Automated Immunocytochemistry for the Bond - CELP-LP-056-NWL</p> <p>Using antibodies for:</p> <p>Treponema Pallidum</p> <p>TTF-1</p> <p>TRAP</p> <p>Vimentin</p>	<p>X-Histo</p>



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological examinations for the purpose of clinical diagnosis</u> (cont'd)	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:	X-Histo
In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections (cont'd)	Identification of cellular or tissue constituents (antigens) by means of antigen antibody interactions:	<u>Automated Immunocytochemistry Ventana. CELP-LP-205-NWL</u>	
	Detection anaplastic lymphoma kinase (ALK) protein in NSCLC	Alk-1 (Lung)	
	Identification of mutant protein BRAF V600E	BRAF	
	Estrogen receptor	ER	
	Heparan sulfate proteoglycan	Glypican 3	
	Cerb B2 in breast and GI	HER2	
	Identification of mismatch repair protein	MSH2 (25D12)	
	Identification of mismatch repair protein	MSH6	
	Identification of mismatch repair protein	MLH-1 (ES05)	
	Identification of mismatch repair protein	PMS 2	
	Trophoblastic disease	P57	
	Programme cell death ligand 1	PDL-1	
	Progesterone receptor	PR	
	Renal Cell Carcinoma	Renal Cell Carcinoma	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological examinations for the purpose of clinical diagnosis</u> (cont'd)	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:	X-Histo
In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections. (cont'd)	Identification of cellular or tissue constituents (antigens) by means of antigen antibody interactions (cont'd): Squamous cell carcinoma Marker of embryonic stem cell pluripotency	<u>Automated Immunocytochemistry Ventana. CELP-LP-205-NWL:</u> SALL-4 SOX-2	
Body fluids	<u>Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis</u> Examination of cellular material in order to identify or exclude morphological and cytological abnormalities Demonstration of: Cells (nuclei and cytoplasm) and micro-organisms	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for preparation, staining and reporting <u>Manual techniques:</u> Rapid Diff Quick - Staining Methods for Non-Gynae - CELP-LP-030-NWL Staining Methods – Cytology CELP-LP-039-NWL Automated staining and coverslipping using Leica CV5030 (coverslipper) Leica ST5020 (autostainer) Autostainer and Coverslipper (CELP-LP-207-NWL) MGG, Papanicolaou staining CELP-LP-207-NWL	M-FNA X-Histo



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HUMAN BODY TISSUE AND FLUIDS (cont'd) Body Fluids (cont'd)	<p><u>Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Examination of cellular material in order to identify or exclude morphological and cytological abnormalities (cont'd)</p> <p>Demonstration of: Cells (nuclei and cytoplasm) and micro-organisms (cont'd)</p>	<p>In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for preparation, staining and reporting:</p> <p><u>Manual techniques:</u></p> <p>Sample preparation - Hologic T2000: T2000 LBC Processor - Laboratory Equipment (General Use & Maintenance) - CELP-LP-076-NWL</p> <p>In the preparation of: Preparation of Anal & Vaginal LBC - CELP-LP-682-NWL</p> <p>Sample preparation - Thermo Cytospin 2, Shandon Heraeus Megafuge 40R: Cytospin - Laboratory Equipment (General Use & Maintenance) - CELP-LP-062-NWL</p> <p>Centrifuge - Laboratory Equipment (General Use & Maintenance) - CELP-LP-075-NWL</p> <p>Bronchoalveolar (BAL & Wash) - Specimen Preparation - CELP-LP-059-NWL</p> <p>Cerebrospinal Fluid (CSF) - Specimen Preparation - CELP-LP-060-NWL</p>	X-Histo



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HUMAN BODY TISSUE AND FLUIDS (cont'd) Body Fluids (cont'd)	<p><u>Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Examination of cellular material in order to identify or exclude morphological and cytological abnormalities (cont'd)</p> <p>Demonstration of: Cells (nuclei and cytoplasm) and micro-organisms (cont'd)</p>	<p>In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for preparation, staining and reporting:</p> <p><u>Manual techniques:</u></p> <p>In the preparation of:</p> <p>Serous & Miscellaneous Fluid - Specimen Preparation - CELP-LP-061-NWL</p> <p>Urine - Specimen Preparation - CELP-LP-063-NWL</p> <p>Sputum - Specimen Preparation - CELP-LP-064-NWL</p> <p>Synovial Fluid - Preparation - CELP-LP-065-NWL</p> <p>Fine Needle Aspiration Cytology - CELP-LP-040-NWL</p> <p>Cell Block & Clot Processing of Cytology Specimens - CELP-LP-080-NWL</p> <p>Papanicolaou & May Grünwald Giemsa Staining Methods - Cytology - CELP-LP-039-NWL</p> <p>Taking and Reporting Fine Needle Aspirate CELP-CP-001-NWL Microscopy Screening and Reporting CELP-LP-042-NWL</p>	X-Histo M-FNA



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HUMAN BODY TISSUE AND FLUIDS (cont'd) Digital Images from slides prepared in house as above	<u>Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for preparation, staining and reporting: Interpretive/diagnostic microscopy - Olympus: BH2, BX41, BX45, BX50, BX51, BX40CY, BX 51XT, BX50F4 & BX51TF. Leitz: Laborlux K, Nikon: Eclipse 80i, Eclipse Ci-S, E600 & E400. Leica MZ8: Reporting - CELP-CP-012-NWL	X-Histo
	<u>Morphological assessment and interpretation/diagnosis for:</u> Head and neck, and skin Lung Cardiac Placenta Haematopathology Gastrointestinal pathology Gynaecological pathology	Using digital pathology (slide scanners and viewing software): Phillips IMS Digital Pathology Suite CELP-LP-235-NWL Digital Pathology IMS guide	CXH
	Routine H& E Special stains Immunohistochemistry slides	Phillips SG300 digital slide scanners CELP- LP-232-NWL Use of Philips Digital Scanner SG300	CXH
	Frozen sections	Leica Aperio 82 slide scanner	CXH
	Frozen sections	Leica CS2 slide scanners	CWH, HH
	Megaslides	Glissando 20SL desktop slide scanner CELP-LP-234-NWL Use of Glissando Scanner	CXH
		Interpretive microscopy using documented in-house procedures according to minimum recommendation by manufacturers; CELP-LP-233-NWL Digital Pathology workflow CELP-CP-012-NWL Reporting SOP.	CXH



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<p>HUMAN BODY FLUIDS AND TISSUES</p> <p>Bone marrow, peripheral blood), bone marrow (lithium heparin), bone marrow (preservative-free heparin plus tissue culture medium), CSF, pleural effusions, ascetic fluid, fine needle aspirates (FNA), endobronchial ultrasound (EBUS), bronchoalveolar lavage (BAL), whole lymph nodes/tissue samples, rare fluids (e.g. vitreous fluids)</p>	<p><u>Immunophenotyping examination procedures for the purposes of clinical diagnosis</u></p> <p>Examination of haematopoetic cells in order to identify the lineage and stage of maturation of the abnormal proliferating cells in the diagnosis and management of AML, ALL, LPD, MPD, CLL, MDS, MM, Non-Hodgkin lymphoma and PNH</p>	<p>Documented in house methods and manufacturer's instructions for flow cytometry using BD FacsCanto</p> <p><u>Manual sample preparation, sample set up, mixing of antibody cocktails</u></p>	
	Acute leukaemia screening	Immunophenotyping for Haematological Malignancies - CELP-LP-107-HMS	H-Immunop
	Classification of acute leukaemia	Using antibodies for: CYT MPO, CD79a, CD34, CD19, CD7, smCD3, CYCD3, CD45	H-Immunop
	Chronic lymphoproliferative screening	CD117, CD58, CD66c, CD10, CD38, CD20, NUC TDT, CYT U, CD22, CD9, smIg LAMBDA, smLg KAPPA, CD1a, CD42a/CD61, CD64, CD99, CD8, CD11b, CD300e, HLA-DR, CD14, CD71, CD235a, CD36, CD105, CD56, CD123, CD64, CD3, CD4, CD5, CD15	H-Immunop
	Classification of chronic lymphoproliferative disorders	CD8, smIgLAMBDA, smIgKappa, CD56, CD5, CD19, TCRGammadelta, smCD3, CD38, CD20, CD4, CD45	H-Immunop
		FMC7, CD10, CD23, CD79b, CD22, CD19, CD43, CD25, CD200, CD81, CD103, CD305, CD11c, CD27, CD49d, CD7, CD57, CD3, CD138, CD16, CYT Kappa, CYT Lambda, CD2, CD28, TCRAIphabeta, CD27, CD38	H-Immunop



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Bone marrow (EDTA), peripheral blood (EDTA), bone marrow (lithium heparin), bone marrow (preservative-free heparin plus tissue culture medium), CSF, pleural effusions, ascetic fluid, fine needle aspirates (FNA), endobronchial ultrasound (EBUS), bronchoalveolar lavage (BAL), whole lymph nodes/tissue samples, rare fluids (e.g. vitreous fluids) (cont'd)</p>	<p><u>Immunophenotyping examination procedures for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Examination of haematopoetic cells in order to identify the lineage and stage of maturation of the abnormal proliferating cells in the diagnosis and management of AML, ALL, LPD, MPD, CLL, MDS, MM, Non-Hodgkin lymphoma and PNH (cont'd)</p> <p>Testing for the presence of PNH clones in Red blood cell and White blood cell populations:</p> <p>Red blood cells</p> <p>White blood cells</p>	<p>Documented in house methods and manufacturer's instructions for flow cytometry using BD FacsCanto</p> <p><u>Manual sample preparation, sample set up, mixing of antibody cocktails</u></p> <p><u>PNH Analysis:</u></p> <p>Detection of Paroxysmal Nocturnal Haemoglobinuria by Flow Cytometry - CELP-LP-106-HMS</p> <p>Using antibodies for: CD59 and CD235a</p> <p>FLAER, CD14, CD33, CD64, CD45, CD15, CD24</p>	<p>H- Immunop</p> <p>H- Immunop</p> <p>H- Immunop</p>



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HUMAN BODY FLUIDS / TISSUES / CELLULAR MATERIAL	<u>Molecular Diagnostics:</u> <u>DNA and RNA profiling for detection of abnormal sequences for clinical diagnosis</u>	Documented in house methods and manufacturer's instructions for molecular diagnostics	
Whole blood (EDTA) Bone Marrow (EDTA) Lyophilised cells	Sample processing for storage of cell lysate	QIAGEN Tissue Lyser CELP-LP-097-HMS	H-MOL
Whole blood (EDTA) Bone marrow (EDTA)	Mononuclear cell isolation	Lymphoprep cell isolation solution CELP-LP-090-HMS	H-MOL
Whole blood (EDTA) Bone marrow (EDTA)	CD3 T-cell separation	AutoMacs Pro CELP-LP-200-HMS	H-MOL
Whole blood (EDTA) Bone marrow (EDTA) Lymphoprep cell sample Cell lysate Lyophilised cells FFPE tissue CD3 T-cell separated sample	Extraction and storage of DNA and RNA	DNA & RNA Extraction - QIASymphony, Eppendorf Micro-centrifuge - CELP-LP-164-HMS	H-OL
		Manual DNA Extraction from FFPE Tissue using QIAGEN QIAmp DNA FFPE Tissue kit CELP-LP-120-HMS	H-MOL
		Manual DNA extraction using the QIAGEN QIAmp DNA mini kit CELP-LP-093-HMS	H-MOL
		Manual RNA extraction using the QIAGEN RNeasy Mini kit CELP-LP-098-HMS	H-MOL
RNA extracted from sources as above	cDNA synthesis from RNA	cDNA synthesis using LunaScript Reverse Transcriptase CELP-LP-099-HMS	H-MOL



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HUMAN BODY FLUIDS / TISSUES / CELLULAR MATERIAL (cont'd)	<u>Molecular Diagnostics: DNA and RNA profiling for detection of abnormal sequences for clinical diagnosis</u> (cont'd)	Documented in house methods and manufacturer's instructions for molecular diagnostics	
cDNA prepared from sources as above	BCR::ABL1 translocation identification	Multiplex PCR using the QIAxcel Advanced analyser for capillary electrophoresis CELP-LP-096-HMS CELP-LP-104-HMS	H-MOL
	BCR::ABL1 TK Domain Mutation (TKD) Analysis – Sanger sequencing	In-house BCR::ABL1 TKD Sanger Sequencing using the Applied Biosystems 3500 XL DX analyser CELP-LP-103-HMS	
		Sanger Sequencing analysis using the Applied Biosystems SeqScape software CELP-LP-159-HMS	
cDNA prepared from peripheral blood or bone marrow	<i>BCR::ABL1</i> tyrosine kinase domain (TKD) analysis - NGS	In-house BCR::ABL1 TKD NGS using the Illumina MiSeq analyser CELP-LP-218-HMS CELP-LP-227-HMS	H-MOL
cDNA prepared from peripheral blood or bone marrow	BCR::ABL1 e1a2 transcript quantitative monitoring (Minimal Residual Disease monitoring)	Thermofisher QuantStudio 5 RT-qPCR analyser using EAC modified e1a2 RT-qPCR assay and IDT synthetic dsDNA standards. CELP-LP-100-HMS CELP-LP-195-HMS	H-MOL
cDNA prepared from peripheral blood or bone marrow	BCR::ABL1 e19a2 transcript quantitative monitoring (Minimal Residual Disease Monitoring)	Thermofisher QuantStudio 5 RT-qPCR analyser using EAC modified e19a2 RT-qPCR assay and IDT synthetic dsDNA standards. CELP-LP-100-HMS CELP-LP-195-HM	H-MOL
	BCR::ABL1 reporting	Reporting and communicating MRD results CELP-LP-102-HMS CELP-LP-088-HMS	H-MOL



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HUMAN BODY FLUIDS / TISSUES / CELLULAR MATERIAL (cont'd)	<u>Molecular Diagnostics: DNA and RNA profiling for detection of abnormal sequences for clinical diagnosis</u> (cont'd)	Documented in house methods and manufacturer's instructions for molecular diagnostics	
DNA as prepared from whole blood (EDTA) DNA received from external sources	Detection of the APOE ε2 haplotype associated with dyslipidaemia (Type III hyperlipoproteinaemia)	TaqMan SNP genotyping assays on the QuantStudio 5 Real-Time PCR System using primers prepared in-house CELP-LP-117-HMS	H-MOL
DNA as prepared from whole blood (EDTA), Bone Marrow (EDTA), lyophilised cells, FFPE and lymphoprep sample from whole blood (EDTA) and bone marrow (EDTA)	Clonality assessment of suspected T- or B-Cell lymphoproliferative disorders: IGH and IGK B-cell clonality TCR Gamma clonality	Commercial kits (InVivoScribe IdentiClone) fragment analysis CELP-LP-091-HMS Applied Biosystems 3500 XL DX analyser CELP-LP-091-HMS CELP-LP-088-HMS Data analysis using GeneMapper	H-MOL
DNA extracted from whole blood (EDTA) and bone marrow (ETA)	Assessment of AML prognostic markers FLT3 ITD FLT3 TKD NPM1 variant status	FLT3 ITD and TKD variant analysis using LeukoStrat CDx FLT3 (Invivoscribe) Mutation Analysis kit Fragment analysis performed using Applied Biosystems 3500 XL DX analyser CELP-LP-163-HMS NPM1 variant analysis using in-house method and AllTaq Master Mix Kit for <i>NPM1</i> fragment analysis Fragment analysis performed using Applied Biosystems 3500 XL DX analyser CELP-LP-201-HMS Data analysis using GeneMapper CELP-LP-163-HMS CELP-LP-201-HMS CELP-LP-088-HMS	H-MOL



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<p>HUMAN BODY FLUIDS / TISSUES / CELLULAR MATERIAL (cont'd)</p> <p>DNA from peripheral blood (EDTA), bone marrow (EDTA), lyophilised cells or CD3 T-cell separation</p>	<p><u>Molecular Diagnostics:</u> <u>DNA and RNA profiling for detection of abnormal sequences for clinical diagnosis</u> (cont'd)</p> <p>Chimerism Analysis</p>	<p>Documented in house methods and manufacturer's instructions for molecular diagnostics</p> <p>Powerplex 16HS Chimerism Assessment DNA Fragment Size Analysis using Capillary Electrophoresis Applied Biosystems 3500 XL DX analyser and PCR CELP-LP-158-HMS</p> <p>Chimerism analysis using ChimerMarker software CELP-LP-158-HMS CELP-LP-088-HMS</p>	H-MOL
<p>DNA from peripheral blood (EDTA), bone marrow (EDTA) or lyophilised cells</p>	<p>MPN NGS Panel: Targeted capture of genes involved in Myeloproliferative Neoplasms: KRAS NRAS SRSF2 U2AF1</p>	<p>AmpliSeq for Illumina Library prep NGS sequencing using the Illumina MiSeq: CELP-LP-190-HMS</p> <p>MPN analysis using Illumina Connected Insights software CELP-LP-190-HMS CELP-LP-088-HMS</p>	H-MOL
<p>DNA from peripheral blood (EDTA), bone marrow (EDTA) or lyophilised cells</p>	<p>Myeloid NGS Panel: Targeted capture of genes involved in Myeloid Leukaemias and Myelodysplasia - detection of small sequence variation by NGS panel</p>	<p>Targeted gene capture using the ThermoFisher OncoPrint Myeloid panel on the Ion Chef and S5 sequencer CELP-LP-203-HMS</p> <p>Myeloid NGS analysis using Ion reporter CELP-LP-208-HMS CELP-LP-088-HMS</p>	H-MOL



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<p>HUMAN BODY TISSUES / CELLULAR MATERIAL (cont'd)</p> <p>Glutaraldehyde fixed nerve, Glutaraldehyde fixed renal biopsies, Glutaraldehyde fixed duodenal biopsies, Glutaraldehyde fixed muscle biopsies, wax re-processed blocks and slides</p>	<p><u>Electron microscopic examinations for the purpose of clinical diagnosis</u></p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p>	<p>In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:</p> <p><u>Tissue dissection & Sample preparation:</u></p> <p>Specimen dissection - CELP-LP-124-X</p> <p>Processing paraffin wax blocks for TEM - CELP-LP-133-X</p> <p>Reprocessing paraffin wax section for TEM - CELP-LP-134-X</p> <p>Followed by either:</p> <p><u>Manual sample processing:</u></p> <p>Routine Processing to Spurr Epoxy Resin - CELP-LP-132-X</p> <p>OR</p> <p><u>Automated sample processing - Leica EM TP:</u></p> <p>Automatic processing with two Leica processors - CELP-LP-135-X</p>	<p>X-EM</p> <p>X-EM</p> <p>X-EM</p> <p>X-EM</p> <p>X-EM</p>



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HUMAN BODY TISSUES / CELLULAR MATERIAL (cont'd)	<u>Electron microscopic examinations for the purpose of clinical diagnosis</u> (cont'd)	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:	
Resin embedded cells/tissue biopsies	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	<u>Section cutting</u> - Preparation of resin embedded tissue blocks for ultramicrotomy - CELP-LP-136-X Preparation of glass knives for ultramicrotomy - CELP-LP-137-X Preparation of semi-thin (thick) survey sections for light microscopy - CELP-LP-138-X Preparation of ultra-thin (thin) sections for Transmission Electron Microscopy - CELP-LP-139-X	X-EM X-EM X-EM X-EM
Semi-thin sections of resin embedded cells/tissue biopsies	Toluidine blue stain for overview staining	<u>Manual staining</u> : Staining semi-thin (thick) survey sections for examination by light microscopy - CELP-LP-140-X	X-EM
Ultra-thin sections of resin embedded cells/tissue biopsies		Staining ultra-thin (thin) sections with heavy metals for Transmission Electron Microscopy - CELP-LP-141-X	X-EM



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<p>HUMAN BODY TISSUES / CELLULAR MATERIAL (cont'd)</p> <p>Ultra-thin sections of resin embedded cells/tissue biopsies</p>	<p><u>Electronmicroscopic examinations for the purpose of clinical diagnosis</u> (cont'd)</p>	<p>In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:</p> <p><u>Electronmicroscopy & digital image capture</u> - Hitachi HT7800 Transmission Electron Microscope Digital camera AMT XR80</p> <p>Operation & Maintenance of the Hitachi H7800 Transmission Electron Microscope - CELP-LP-237-X</p> <p>Digital Imaging on the Transmission Electron Microscope - CELP-LP-144-X</p> <p><u>Interpretation/Reporting:</u></p> <p>Handling and reporting surgical tissues - CELP-LP-153-X</p>	<p>X-EM</p> <p>X-EM</p> <p>X-EM</p>
	<p><u>Cytogenetic examination for the purposes of clinical diagnosis</u></p>	<p>Karyotyping analysis of G-banded chromosomes</p> <p>Manual slide making for Zeiss Primo Star phase microscope: Cytogenetics sample set up CELP-LP-110-HMS Cytogenetics harvest CELP-LP-113-HMS Cytogenetics slide-making CELP-LP-114-HMS</p> <p>Cytogenetics Banding - CELP-LP-087-HMS</p> <p>Image capture for chromosome preparations using Leica GSL120 and Leica CytoVision karyotyping stations: Use of Cytogenetic Imaging Systems CELP-LP-001-HMS</p>	<p>H-CytoG</p> <p>H-CytoG</p> <p>H-CytoG</p>



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Fixed cells from bone marrow, peripheral blood and CSF/ Paraffin Embedded Tissue (FFPE)	FISH analysis for the detection of structural chromosome rearrangements and copy number changes	Manual FISH slide preparation, pre-treatment and probe hybridisation using commercial probes: Thermobrite Hybridisation systems. Commercial FISH Probes from Metasystems, Cytocell and Kreatech. Cytogenetics FISH set-up CELP-LP-111-HMS	H-CytoG
		Cytogenetics Manual FFPE FISH - CELP-LP-115-HMS	H-CytoG
		FISH analysis using Zeiss Axio Imager M2 and ISIS (Metasystems) software	H-CytoG
		Use of Cytogenetic Imaging Systems - CELP-LP-001-HMS	
Bone marrow, peripheral blood		CD138+ cell enrichment in plasma cell myeloma prior to FISH: Automated cell separation using AutoMACS Pro Miltenyi Biotech CELP-LP-185-HMS	H-CytoG
		Reporting and Authorisation of G-Banding and FISH Reports in Cytogenetics CELP-LP-122-HMS	H-CytoG
		Guidelines for the Analysis of G-Banded chromosomes and fluorescence in situ hybridisation (FISH) samples from patients with haematological neoplasms - CELP-LP-179-HMS	H-CytoG
END			