


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL</p> <p>9615</p> <p>Accredited to ISO 15189:2012</p>	<p>Imperial College Healthcare NHS Trust operating as North West London Pathology</p> <p>Issue No: 007 Issue date: 28 September 2021</p>	
	<p>Charing Cross Hospital Rm 2L20, Pathology Quality Office Fulham Palace Road London W6 8RF</p>	<p>Contact: Michael Donovan Tel: +44 (0) 20 8321 6153 E-Mail: m.donovan@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	Sarah Lee (as above)	Histopathology Electron Microscopy	X-Histo X-EM X-Cyto
Hammersmith Hospital Du Cane Road East Acton London W12 0HS	Sarah Lee (as above)	Frozen section histology Molecular Diagnostics Minimal Residual Disease Immunophenotyping Cytogenetics	H-Histo H-MDL H-MRD H-Immunop H-CytoG
St. Mary's Hospital Praed Street Paddington London W2 1NY	Sarah Lee (as above)	Frozen section histology	M-Histo
Chelsea and Westminster 369 Fulham Road London SW10 9NH	Sarah Lee (as above)	Frozen section histology	C-Histo



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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	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 - CEL-CP-033-NWL</p> <p>Bladder - CEL-CP-042-NWL</p> <p>Breast - CEL-CP-031-NWL</p> <p>Central and peripheral nervous system tumours - CEL-CP-040-NWL</p> <p>Head & Neck - CEL-CP-028-NWL</p> <p>Kidney - CEL-CP-043-NWL</p> <p>Osteoarticular - CEL-CP-034-NWL</p> <p>Penis - CEL-CP-044-NWL</p> <p>Prostate - CEL-CP-045-NWL</p> <p>Salivary gland - CEL-CP-029-NWL</p> <p>Skin - CEL-CP-027-NWL</p> <p>Testis - CEL-CP-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>



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		Gynaecological SOP - CEL-CP-035-NWL	X-Histo
		Respiratory Specimens cut-up SOP - CEL-CP-037-NWL	X-Histo
		Haematopathology cut-up SOP - CEL-CP-047-NWL	X-Histo
		Hepatopancreaticobiliary SOP - CEL-CP-051-NWL	X-Histo
		Kidney Transplant Resection - CEL-CP-057-NWL	X-Histo
		Pancreas Transplant Resection - CEL-CP-058-NWL	X-Histo
		Thyroid and Parathyroid - CEL-CP-061-NWL	X-Histo
		Temporal Artery Samples - CEL-CP-063-NWL	X-Histo
		Upper G.I Cancer -CEL-CP-012-NWL	X-Histo
		Colorectal Specimens - CEL-CP-019-NWL	X-Histo
		Liver SOP - CEL-CP-020-NWL	X-Histo
		Placenta SOP - CEL-CP-022-NWL	X-Histo
		Bowel Cancer Screening Programme (BCSP) Specimen Handling - CEL-CP-065-NWL	X-Histo
		Gallbladder and Appendices - CEL-CP-066-NWL	X-Histo
		Specimen transfer SOP CEL-LP-303-NWL	X-Histo



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Tissues: biopsy, excision and resection</p> <p>Fresh tissue</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>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 - CEL-LP-240-NWL</p> <p><u>Frozen sections:</u></p> <p>Bright OTF 5000 Cryostat Preparing Tissue for Frozen Section, Cryotomy and Diagnosis - CEL-LP-328-NWL</p> <p>Thermo Cryotome FSE Leica CM1900 Cryostat: Preparing Tissue for Frozen Section, Cryotomy and Diagnosis - CEL-LP-328-NWL</p> <p>Thermo Cryotome FSE Thermo CryoStar NX-50: Frozen Section - CEL-LP-733-NWL</p> <p>Thermo Cryotome SME: Frozen Section - CEL-LP-328-NWL</p> <p>Thermo Cryotome FSE : Mohs - CEL-LP-459-C</p> <p>Frozen Section - CEL-LP-449-C</p>	<p>X-Histo</p> <p>H-Histo</p> <p>X-Histo</p> <p>X-Histo</p> <p>M-Histo</p> <p>C-MOHS</p> <p>C-Histo</p>



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological examinations for the purpose of clinical diagnosis (cont'd)</u>	In-house documented methods for macroscopic and microscopic examination incorporating manufacturer's instructions where relevant for dissection, processing, embedding, staining and reporting:	
Formalin fixed tissue processed to paraffin wax (FFPE), Fresh tissue, Frozen Tissue, Cell blocks	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	<u>Tissue processing</u> - Leica Peloris 3 CEL-LP-720-NWL	X-Histo
		<u>Embedding</u> -: HistoCore Arcadia H	
		Embedding Protocol - CEL-LP-712-NWL	X-Histo
		<u>Microtomy</u> - Leica RM2255. Thermofisher - Finesse ME	
		Microtomy Procedure - CEL-LP-718-NWL	X-Histo
		<u>Automated staining and coverslipping</u> - Leica ST5020 (autostainer), Leica CV5030 (coverslipper);, <u>Autostainer and Coverslipper (CEL-LP-736-NWL)</u>	
In house preparations of 10% Neutral Buffered Formalin fixed tissue processed to paraffin wax (FFPE) tissue sections.	Special staining of Histopathology examinations to assist in detection of clinical abnormalities:	<u>Automated routine staining</u> - Leica ST5020:	
		<u>Automated routine staining</u> - Ventana HE 600	
		Ventana HE 600 System - CEL-LP-732-NWL	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 (cont'd)</u></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>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 - CEL-LP-459-C</p> <p><u>Manual techniques:</u></p> <p>Alcian Blue - CEL-LP-064-NWL</p> <p>Alcian Blue Diastase Periodic Acid Schiff - CEL-LP-445-NWL</p> <p>Alcian Blue including Hyaluronidase digestion - CEL-LP-185-NWL</p> <p>Chromotrope Aniline Blue Stain - CEL-LP-069-NWL</p> <p>Elastic Picro Sirius - CEL-LP-378-NWL</p>	<p>C-MOHS</p> <p>X-Histo</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 (cont'd)</u></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>	X-Histo
	<p>Special staining of Histopathology examinations to assist in detection of clinical abnormalities (cont'd)</p>	<p><u>Manual techniques (cont'd):</u></p>	
	<p>Haematopoietic cells</p>	<p>Giemsa Stain CEL-LP-383-NWL</p>	
	<p>Gram +/- organisms</p>	<p>Gram Stain - CEL-LP-077-NWL</p>	
	<p>Fibrin/connective tissue/muscle</p>	<p>Haematoxylin Van Gieson Stain - CEL-LP-082-NWL</p>	
	<p>Myelin sheaths/nissl substance/neurones</p>	<p>Luxol Fast Blue - CEL-LP-159-NWL</p>	
	<p>Argentaffin/melanin</p>	<p>Masson Fontana - CEL-LP-206-NWL</p>	
	<p>Argentaffin/melanin</p>	<p>Masson Fontana Stain - CEL-LP-206-NWL</p>	
	<p>Helicobacter Pylori</p>	<p>Modified Giemsa Stain - CEL-LP-556-NWL</p>	
	<p>Neutral mucins/polysaccharides/fungi/basement membranes/glycogen</p>	<p>Periodic Acid Schiff +/- Diastase Stain - CEL-LP-377-NWL</p>	
	<p>Haemosiderin/Iron</p>	<p>Perls Stain - CEL-LP-053-NWL</p>	
	<p>Mast cell granules</p>	<p>Toluidine Blue - CEL-LP-409-NWL</p>	
	<p>Calcium salts</p>	<p>Von Kossa - CEL-LP-231-NWL</p>	
	<p><i>Mycobacterium leprae</i></p>	<p>Wade Fite - CEL-LP-230-NWL</p>	
<p><i>Mycobacterium</i> spp. including tuberculosis</p>	<p>Ziehl Neelson - CEL-LP-413-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 (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>Sakura Tissue-Tek Film Automated Coverslipper. SOP: use and maintenance of Sakura Automated Coverlipping Machine - CEL-LP-114-NWL</p> <p>Automated special staining – Dako Artisan Link Pro - Artisan Staining System SOP, CEL-LP-739-NWL:</p>	<p>X-Histo</p> <p>X-Histo</p>
	<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>	<p>Congo Red</p> <p>Jones Hexamine Silver</p> <p>Grocott Methanamine Silver</p> <p>Masson Trichrome</p> <p>Orcein</p> <p>Reticulin</p> <p>Warthin and Starry</p>	
<p>Skin frozen sections</p>	<p>Bullous diseases, pemphigoid, LE - C3c complement</p>	<p>C3c</p> <p>Direct Skin Immunofluorescence: CEL -LP-298-NWL - IF: Receipt, freezing and Slides preparation and CEL-LP-356-NWL - Immunofluorescence Staining Using antibodies for:</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.</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>Bullous diseases, pemphigoid, LE - Fibrinogen</p>	Fibrinogen	X-Histo
	<p>Bullous diseases, pemphigoid, LE - IgA alpha chain</p>	IgA	X-Histo
	<p>Bullous diseases, pemphigoid, LE - IgG gamma chain</p>	IgG	X-Histo
	<p>Bullous diseases, pemphigoid, LE - IgM mu chain</p>	IgM	X-Histo
		<p><u>Automated immunocytochemistry - Bond Max, Bond III:</u></p> <p>Automated Immunocytochemistry for the Bond - CEL-LP-357-H</p> <p>Using antibodies for:</p>	X-Histo
	<p>Fetal liver cells, liver disease</p> <p>Anaplastic large cell lymphoma</p> <p>Corticotrophs. Pituitary tumours.</p>	<p>a-fetoprotein</p> <p>ALK-1</p> <p>ACTH</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.</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>AA-amyloidosis</p> <p>Androgen receptor</p> <p>Glioma / oligodendroglioma</p> <p>Mantle cell lymphoma</p> <p>B and T cells in the mantle and marginal zone</p> <p>B and T cells in the mantle and marginal zone</p> <p>Nuclei of germinal B cells</p> <p>Epithelial 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 Max, Bond III:</u></p> <p>Automated Immunocytochemistry for the Bond - CEL-LP-357-H</p> <p>Using antibodies for:</p> <p>Amyloid A</p> <p>Androgen receptor</p> <p>ATRX</p> <p>bcl-1/Cyclin D1</p> <p>bcl-2</p> <p>bcl-2 alt</p> <p>bcl-6</p> <p>BerEP4</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.</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>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>Dendritic cells, monocytes, macrophages, neutrophils and some 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 Max, Bond III:</u></p> <p>Automated Immunocytochemistry for the Bond - CEL-LP-357-H</p> <p>Using antibodies for:</p> <p>Ca19.9</p> <p>Calcitonin</p> <p>Caldesmon</p> <p>Calretinin</p> <p>Cam5.2</p> <p>CD10</p> <p>CD11c</p>	<p>X-Histo</p>



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	<p>Monocytes and dermal dendritic cells</p>	<p>CD14</p>	
	<p>B cells and follicular dendritic cells</p>	<p>CD19</p>	
	<p>Langerhans cell, dendritic cells and thymocytes</p>	<p>CD1a</p>	
	<p>Vascular endothelial cells</p>	<p>CD105 (Endoglin)</p>	
	<p>Plasmacytoid dendritic cells</p>	<p>CD123</p>	
	<p>Plasma cells</p>	<p>CD138</p>	
	<p>Monocytes and macrophages</p>	<p>CD163</p>	



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	<p>Pan T cells</p>	<p>CD2</p>	
	<p>Pan B cells</p>	<p>CD20</p>	
	<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>	



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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 (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>Endothelial cells</p> <p>Immature T and B cells, thymocytes, plasma cells</p> <p>T helper cells, monocytes, macrophages and dendritic cells</p> <p>Platelets, megakaryocytes, endothelial cells</p> <p>T cells, monocytes, granulocytes and some B cells</p> <p>T and B cells</p> <p>T cells and some 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 Max, Bond III:</u></p> <p>Automated Immunocytochemistry for the Bond - CEL-LP-357-H</p> <p>Using antibodies for:</p> <p>CD34</p> <p>CD38</p> <p>CD4</p> <p>CD42b</p> <p>CD43 MT1</p> <p>CD45 (LCA)</p> <p>CD5</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.</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>Neurons, glia, skeletal muscle and NK cells</p> <p>NK cells</p> <p>Macrophages, myeloid and histiocytic cells</p> <p>Monocytes and macrophages</p> <p>T cells and NK cells</p> <p>B cells</p> <p>Cytotoxic T cells</p> <p>Intestinal epithelium</p> <p>Epiithelial 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 Max, Bond III:</u></p> <p>Automated Immunocytochemistry for the Bond - CEL-LP-357-H</p> <p>Using antibodies for:</p> <p>CD56 (N-CAM)</p> <p>CD57 (Leu7)</p> <p>CD68 (KP1)</p> <p>CD68 (PGM1)</p> <p>CD7</p> <p>CD79a</p> <p>CD8</p> <p>CDX2</p> <p>CEA (poly)</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.</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>Neuroendocrine cells</p> <p>Mast cells and GIST</p> <p>Overexpression in hematopoietic tumours</p> <p>Basement membranes</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>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 Max, Bond III:</u></p> <p>Automated Immunocytochemistry for the Bond - CEL-LP-357-H</p> <p>Using antibodies for:</p> <p>Chromogranin A</p> <p>C-kit CD117</p> <p>C-Myc</p> <p>Collagen IV</p> <p>Cytokeratin AE1/AE3</p> <p>Cytokeratin 34BE12</p> <p>Cytokeratin 5</p> <p>Cytokeratin 8/18</p> <p>Cytokeratin 14</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.</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>Basal cells of complex epithelia</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>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 Max, Bond III:</u></p> <p>Automated Immunocytochemistry for the Bond - CEL-LP-357-H</p> <p>Using antibodies for:</p> <p>Cytokeratin 17</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>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.</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>Smooth, skeletal and cardiac muscle</p> <p>GIST</p> <p>Latent EBV RNA within B cells</p> <p>Epithelial tissue</p> <p>Epithelial cells</p> <p>Endothelial cells</p> <p>Dermatofibroma</p> <p>FSH in pituitary lesions</p> <p>T 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 Max, Bond III:</u></p> <p>Automated Immunocytochemistry for the Bond - CEL-LP-357-H</p> <p>Using antibodies for:</p> <p>Desmin</p> <p>DOG-1</p> <p>EBER ISH</p> <p>E-cadherin</p> <p>EMA</p> <p>Factor VIII</p> <p>Factor XIIIa</p> <p>FSH</p> <p>Fox P3</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.</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>Gastrin producing cells in the stomach</p> <p>Bladder carcinoma</p> <p>Apocrine epithelia of skin and breast</p> <p>Astrocytes, Schwann cells, glial cells, satellite cells</p> <p>Glucagon secreting cells</p> <p>Cytotoxic T cells and NK cells</p> <p>GH in pituitary lesions</p> <p>K light chain mRNA</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 Max, Bond III:</u></p> <p>Automated Immunocytochemistry for the Bond - CEL-LP-357-H</p> <p>Using antibodies for:</p> <p>Gastrin</p> <p>Gata-3</p> <p>GCDFP-15 (BRST2)</p> <p>GFAP (GA5)</p> <p>Glucagon</p> <p>Granzyme B</p> <p>Growth Hormone</p> <p>Kappa (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.</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>Helicobacter pylori in stomach</p> <p>Mesothelial cells</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>Glioma / oligodendroglioma</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 Max, Bond III:</u></p> <p>Automated Immunocytochemistry for the Bond - CEL-LP-357-H</p> <p>Using antibodies for:</p> <p>H. pylori</p> <p>HBME-1 (Meso)</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>IDH-1</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.</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>Automated immunocytochemistry - Bond Max, Bond III:</u></p> <p>Automated Immunocytochemistry for the Bond - CEL-LP-357-H</p> <p>Using antibodies for:</p>	<p>X-Histo</p>
	<p>Surface IgA alpha - Myeloma</p>	<p>IgA (BMT)</p>	
	<p>Surface IgA alpha</p>	<p>IgA (renals)</p>	
	<p>Surface IgD delta chains</p>	<p>IgD</p>	
	<p>Surface IgG gamma</p>	<p>IgG (BMT)</p>	
	<p>Surface IgG gamma</p>	<p>IgG (renals)</p>	
	<p>IgG4 positive plasma cells</p>	<p>IgG4</p>	
	<p>Surface IgM mu chains</p>	<p>IgM (BMT)</p>	
	<p>Surface IgM mu chains</p>	<p>IgM (renals)</p>	
	<p>Ovarian granulosa cells, testicular sertoli and leydig cells</p>	<p>Inhibin</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.</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>Beta cells of the islets of Langerans in pancreas</p> <p>Surface immunoglobulin on B cells</p> <p>Plasma cells</p> <p>Proliferating cells</p> <p>Lambda light chain mRNA</p> <p>Surface immunoglobulin on B cells</p> <p>Surface immunoglobulin on B cells</p> <p>Basement membranes</p> <p>Langerhans 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 Max, Bond III:</u></p> <p>Automated Immunocytochemistry for the Bond - CEL-LP-357-H</p> <p>Using antibodies for:</p> <p>Insulin</p> <p>Kappa (Lymphoma)</p> <p>Kappa (PC)</p> <p>Ki67 (K2)</p> <p>Lambda (ISH)</p> <p>Lambda (PC)</p> <p>Lambda (Lymphoma)</p> <p>Laminin</p> <p>Langerin</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.</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>Pre B and T cells</p> <p>LH in pituitary lesions</p> <p>Detects circulating / met breast cancer cells</p> <p>Dendrites of post-mitotic neurons</p> <p>Mast cells</p> <p>Melanocytes, junctional and blue nevus cells</p> <p>Melanocytes/ melanomas</p> <p>Mesothelial 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 Max, Bond III:</u></p> <p>Automated Immunocytochemistry for the Bond - CEL-LP-357-H</p> <p>Using antibodies for:</p> <p>Lef-1</p> <p>Luteinizing Hormone</p> <p>Mammaglobin</p> <p>Map-2</p> <p>Mast Cell Tryptase</p> <p>Mel Sp Ag (HMB45)</p> <p>Melan A</p> <p>Mesothelin</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.</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>Some lymphocytes, cortical thymocytes, granulosa cells of the ovary, Langerhans islet cells, sertoli cells</p> <p>Glioma / oligodendroglioma</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 Max, Bond III:</u></p> <p>Automated Immunocytochemistry for the Bond - CEL-LP-357-H</p> <p>Using antibodies for:</p> <p>Mic-2</p> <p>MGMT</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.</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>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>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 Max, Bond III:</u></p> <p>Automated Immunocytochemistry for the Bond - CEL-LP-357-H</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>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.</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>Neurones, Neuronal processes, peripheral nerves and ganglion cells</p> <p>Neutrophils and neutrophil precursor</p> <p>Neuroendocrine cells</p> <p>Neuronal cell types</p> <p>Oligodendroglial progenitor cells</p> <p>B cells</p> <p>Embryonic stem and germ cells</p> <p>HPV</p> <p>P40 protein in squamous cell carcinomas</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 Max, Bond III:</u></p> <p>Automated Immunocytochemistry for the Bond - CEL-LP-357-H</p> <p>Using antibodies for:</p> <p>Neurofilaments</p> <p>Neut. Elastase</p> <p>NSE</p> <p>NeuN</p> <p>OLIG-2</p> <p>OCT-2</p> <p>OCT 3/4</p> <p>P16 (RTU)</p> <p>p40</p>	<p>X-Histo</p>



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
<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 (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>Skin, pancreatic, colon, uterus and epithelial cells. It is also produced by fibroblasts</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>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 Max, Bond III:</u></p> <p>Automated Immunocytochemistry for the Bond - CEL-LP-357-H</p> <p>Using antibodies for:</p> <p>Smad4</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>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.</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>Primitive T and B cells, thymocytes</p> <p>Thyroid follicular cells</p> <p>Treponema Pallidum</p> <p>TSH in pituitary lesions</p> <p>Follicular epithelial cells of the thyroid, type II pneumocytes and Clara cells of the lung</p> <p>Hairy cell Leukaemia</p> <p>T cells and thymocytes</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 Max, Bond III:</u></p> <p>Automated Immunocytochemistry for the Bond - CEL-LP-357-H</p> <p>Using antibodies for:</p> <p>Tdt</p> <p>Thyroglobulin</p> <p>Treponema Pallidum</p> <p>TSH</p> <p>TTF-1</p> <p>TRAP</p> <p>UCHL1 (CD45R0)</p> <p>Vimentin</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.</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 (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>Detection anaplastic lymphoma kinase (ALK) protein in NSCLC</p> <p>Identification of mutant protein BRAF V600E</p> <p>Estrogen receptor</p> <p>Heparan sulfate proteoglycan</p> <p>Cerb B2 in breast and GI</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 Ventana. CEL-LP-647-NWL</u></p> <p>Alk-1 (Lung)</p> <p>BRAF</p> <p>ER</p> <p>Glypican 3</p> <p>HER2</p>	<p>X-Histo</p> <p>X-Histo</p>
	<p>Identification of cellular or tissue constituents (antigens) by means of antigen antibody interactions (cont'd):</p> <p>HPV 6/11</p> <p>HPV 16+</p> <p>Identification of mismatch repair protein</p>	<p>Automated Immunocytochemistry Ventana. CEL-LP-647-NWL (cont):</p> <p>HPV 6/11</p> <p>HPV 16+</p> <p>MLH-1 (ES05)</p>	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological examinations for the purpose of clinical diagnosis (cont'd)</u>	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.	Identification of cellular or tissue constituents (antigens) by means of antigen antibody interactions (cont'd):	Automated Immunocytochemistry Ventana. CEL-LP-647-NWL (cont):	
	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	
	Squamous cell carcinoma	SALL-4	
	Marker of embryonic stem cell pluripotency	SOX-2	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological examinations for the purpose of clinical diagnosis (cont'd)</u>	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 frozen tissue sections	Identification of antigens at a subcellular level by means of fluorescent antibodies	<u>Manual immunofluorescence:</u>	
		Renal IF Staining: CEL -LP-298-NWL - IF: Receipt, freezing and Slides preparation and CEL-LP-356-NWL - Immunofluorescence Staining Using antibodies for:	
	C1q complement	C1q	
	C3c complement	C3c	
	IgA alpha chain	IgA	
	IgG gamma chain	IgG	
	IgM mu chain	IgM	
	Light chain deposition	Kappa	
	Light chain deposition	Lambda	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<p><u>Histopathological examinations for the purpose of clinical diagnosis (cont'd)</u></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>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:</u></p> <p>Reporting - CEL-CP-032-IMP</p>	X-Histo,
Body fluids	<p><u>Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis</u></p> <p>Examination of cellular material in order to identify or exclude morphological and cytological abnormalities</p> <p>Demonstration of: Cells (nuclei and cytoplasm) and micro-organisms</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>Rapid Diff Quick - Staining Methods for Non-Gynae - CEL-LP-030-M Staining Methods – Cytology CEL-LP-281-NWL</p> <p>Automated staining and coverslipping using Leica CV5030 (coverslipper) Leica ST5020 (autostainer) Autostainer and Coverslipper (CEL-LP-736-NWL)</p>	



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HUMAN BODY TISSUE AND FLUIDS (cont'd) Body Fluids	<p><u>Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis</u></p> <p>Examination of cellular material in order to identify or exclude morphological and cytological abnormalities</p> <p>Demonstration of: Cells (nuclei and cytoplasm) and micro-organisms</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>MGG, Papanicolaou staining CEL-LP-736-NWL</p> <p>Automated staining and coverslipping using Leica ST5020</p> <p>MGG, Papanicolaou staining CEL-LP-736-NWL</p> <p>Sample preparation - Hologic T2000: T2000 LBC Processor - Laboratory Equipment (General Use & Maintenance) - CEL-LP-419-NWL</p> <p>In the preparation of: Preparation of Anal & Vaginal LBC - CEL-LP-682-NWL</p> <p>Sample preparation - Thermo Cytospin 2, Shandon Heraeus Megafuge 40R: Cytospin - Laboratory Equipment (General Use & Maintenance) - CEL-LP-365-NWL</p>	<p>X-Histo</p> <p>X-Histo</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Body Fluids</p>	<p><u>Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis</u></p> <p>Examination of cellular material in order to identify or exclude morphological and cytological abnormalities</p> <p>Demonstration of: Cells (nuclei and cytoplasm) and micro-organisms</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>Centrifuge - Laboratory Equipment (General Use & Maintenance) - CEL-LP-415-NWL</p> <p>Bronchoalveolar (BAL & Wash) - Specimen Preparation - CEL-LP-362-NWL</p> <p>Cerebrospinal Fluid (CSF) - Specimen Preparation - CEL-LP-363-NWL</p> <p>Serous & Miscellaneous Fluid - Specimen Preparation - CEL-LP-364-NWL</p> <p>Urine - Specimen Preparation - CEL-LP-367-NWL</p> <p>Sputum - Specimen Preparation - CEL-LP-368-NWL</p> <p>Synovial Fluid - Preparation - CEL-LP-369-NWL</p>	



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Body Fluids</p>	<p><u>Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis</u></p> <p>Examination of cellular material in order to identify or exclude morphological and cytological abnormalities</p> <p>Demonstration of: Cells (nuclei and cytoplasm) and micro-organisms</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>Fine Needle Aspiration Cytology - CEL-LP-282-NWL</p> <p>Cell Block & Clot- Processing of Cytology Specimens - CEL-LP-442-NWL</p> <p>Papanicolaou & May Grünwald Giemsa Staining Methods - Cytology - CEL-LP-281-NWL</p> <p>Taking and Reporting Fine Needle Aspirate CEL-CP-003-NWL Microscopy Screening and Reporting CEL-LP-284-NWL</p>	<p>X-Histo M-FNA</p>



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<p>HUMAN BODY FLUIDS</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)</p>	<p><u>Immunophenotyping examination procedures for the purposes of clinical diagnosis</u></p> <p>Examination of haematopoietic 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 FACS Canto</p> <p><u>Manual sample preparation, sample set up, mixing of antibody cocktails</u></p>	
	Acute leukaemia screening	Immunophenotyping for Haematological Malignancies - CEL-LP-510-H	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, TCRAAlphabeta, 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)</p>	<p><u>Immunophenotyping examination procedures for the purposes of clinical diagnosis (cont'd)</u></p> <p>Examination of haematopoietic 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>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 FACS Canto</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 - CEL-LP-507-H</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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<p>HUMAN BODY FLUIDS / TISSUES / CELLULAR MATERIAL</p> <p>Whole blood (EDTA), bone marrow (EDTA), blood (lithium heparin), bone marrow (lithium heparin), Lymphocyte cell pellets in PBS, Stem cell apheresis in DMSO, lyophilised cells, saliva, FFPE tissue rolls, fresh frozen tissue</p>	<p><u>Molecular Diagnostics: DNA and RNA profiling for detection of abnormal sequences for clinical diagnosis</u></p> <p><u>Extraction & storage of DNA & RNA</u></p>	<p>Documented in house methods and manufacturer's instructions for molecular diagnostics</p>	H-MDL
		<p>DNA & RNA Extraction - Qia Symphony, Eppendorf Micro-centrifuge - CEL-LP-654-H</p>	
<p>DNA and/or RNA from - Whole blood (EDTA), bone marrow (EDTA), blood (lithium heparin), bone marrow (lithium heparin), Lymphocyte cell pellets in PBS, Stem cell apheresis in DMSO, lyophilised cells</p>	<p>Translocation detection for? CML and ALL patients</p>	<p>DNA Extraction from FFPE Tissue - CEL-LP-549-H</p>	H-MDL
		<p>Molecular DNA extraction-Qiagen Manual method - CEL-LP-484-H</p>	H-MDL, H-MRD
		<p>Fresh Frozen (FF) Tissue Processing - CEL-LP-664-H</p>	H-MDL
<p>DNA and/or RNA from - Whole blood (EDTA), bone marrow (EDTA), blood (lithium heparin), bone marrow (lithium heparin), Lymphocyte cell pellets in PBS, Stem cell apheresis in DMSO, lyophilised cells</p>	<p>Translocation detection for? CML and ALL patients</p>	<p><u>Sample preparation - Qiagen Tissue Lyser:</u></p>	H-MRD
		<p>Sample preparation - CEL-LP-492-H</p> <p><u>cDNA Synthesis</u> - Heating Block, Eppendorf Micro-centrifuge</p>	



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<p>HUMAN BODY FLUIDS / TISSUES / CELLULAR MATERIAL (cont'd)</p> <p>DNA and/or RNA from - Whole blood (EDTA), bone marrow (EDTA), blood (lithium heparin), bone marrow (lithium heparin), Lymphocyte cell pellets in PBS, Stem cell apheresis in DMSO, lyophilised cells</p>	<p><u>Molecular Diagnostics: DNA and RNA profiling for detection of abnormal sequences for clinical diagnosis (cont'd)</u></p>	<p>Documented in house methods and manufacturer's instructions for molecular diagnostics</p>	
		<p>cDNA Synthesis - CEL-LP-494-H</p>	H-MRD
		<p><u>Sample preparation - Qiagen Tissue Lyser:</u></p>	H-MDL
		<p>Sample preparation - CEL-LP-492-H</p>	
		<p><u>cDNA Synthesis</u> - Heating Block, Eppendorf Micro-centrifuge</p>	
		<p>cDNA Synthesis - CEL-LP-494-H</p>	
		<p>Followed by either:</p>	
		<p>Multiplex PCR for new patients - QIAxcel - CEL-LP-491-H & CEL-LP-505-H</p>	H-MRD
		<p><u>Multiplex PCR</u> - Veriti Thermocycler, Applied Biosystems 3500 xl DX</p>	H-MDL
		<p>BCR-ABL1 TK Domain Mutation (TKD) Analysis</p>	<p>For either:CEL-LP-503-H</p> <p>a) BCR-ABL1 rare transcript RT-qPCR - CEL-LP-665-H</p> <p>b) BCR-ABL e1a2 RQ PCR analysis - CEL-LP-665-H</p> <p>BCR-ABL1 TKD Mutation Analysis using SeqScape - CEL-LP-643-H</p>
<p>BCR-ABL1 MRD (Minimal Residual Disease)</p>	<p><u>CEL-LP-716-H</u></p>	H-MRD	



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<p>HUMAN BODY FLUIDS / TISSUES / CELLULAR MATERIAL (cont'd)</p> <p>DNA and/or RNA from - Whole blood (EDTA), bone marrow (EDTA), blood (lithium heparin), bone marrow (lithium heparin), Lymphocyte cell pellets in PBS, Stem cell apheresis in DMSO, lyophilised cells</p>	<p><u>Molecular Diagnostics:</u> <u>DNA and RNA profiling for detection of abnormal sequences for clinical diagnosis (cont'd)</u></p>	<p>Documented in house methods and manufacturer's instructions for molecular diagnostics</p> <p><u>Interpretation/Reporting:</u> Reporting and communicating MRD results - CEL-LP-501-H</p>	<p>H-MRD</p>



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<p>HUMAN BODY FLUIDS / TISSUES / CELLULAR MATERIAL (cont'd)</p> <p>DNA and/or RNA from - Whole blood (EDTA), bone marrow (EDTA), blood (lithium heparin), bone marrow (lithium heparin), Lymphocyte cell pellets in PBS, Stem cell apheresis in DMSO, lyophilised cells</p>	<p><u>Molecular Diagnostics: DNA and RNA profiling for detection of abnormal sequences for clinical diagnosis (cont'd)</u></p> <p>Clonality assessment of suspected T or B Cell lymphoproliferative disorders</p>	<p>Documented in house methods and manufacturer's instructions for molecular diagnostics</p> <p><u>DNA & RNA Extraction</u> - Qia Symphony, Eppendorf Micro-centrifuge:</p> <p>CEL-LP-654-H</p> <p>MDL- Lymphoprep Cell Isolation - CEL-LP-474-H</p>	<p>H-MDL</p> <p>H-MDL</p>



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	<p>AML prognostic markers:</p>	<p>Commercial kits (InVivoScribe) fragment analysis - MDL - IGH/TCR Clonality - CEL-LP-475-H</p> <p><u>Testing and analysis</u> - Veriti PCR thermocycler, Life Technologies Genetic analyser ABI3500 and data analysis using GeneMapper:</p>	H-MDL
	<p>FLT3 NPM1</p>	<p>Proflex PCR: FLT3 LeukoStrat CDx Mutation Analysis - CEL-LP-650-H, NPM1 Mutation Analysis -CEL-LP-728-HFLT3 & NPM1 Mutation Analysis - CEL-LP-468-H</p>	H-MDL



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<p>HUMAN BODY FLUIDS / TISSUES / CELLULAR MATERIAL (cont'd)</p> <p>DNA and/or RNA from - Peripheral blood (EDTA), bone marrow (EDTA), blood (lithium heparin), blood (Sodium citrate), bone marrow (lithium heparin), buccal swabs</p>	<p><u>Molecular Diagnostics: DNA and RNA profiling for detection of abnormal sequences for clinical diagnosis (cont'd)</u></p> <p>Post BMT Transplant monitoring:</p>	<p>Documented in house methods and manufacturer's instructions for molecular diagnostics</p> <p><u>T Cell Separation</u> - Automacs:</p>	<p>H-MDL</p>
	<p>Chimerism</p>	<p>MDL-CD3 T cell Separation using AutoMacs Pro - CEL-LP-724-NWL</p> <p>Followed by:</p> <p><u>Manual DNA extraction:</u></p> <p>Molecular DNA extraction-Qiagen Manual method - CEL-LP-484-H</p> <p>Veriti Thermocycler: Kit I and II Chimerism Assessment – DNA Fragment Size Analysis using Capillary Electrophoresis and PCR - CEL-LP-473-H</p>	
<p>DNA and/or RNA from - Peripheral blood (EDTA), bone marrow (EDTA), blood (lithium heparin), blood (Sodium citrate), bone marrow (lithium heparin), Lymphocyte cell pellets in PBS, lyophilised cells</p>	<p>SNP analysis:</p>	<p><u>Testing and analysis</u> - QFPCR using Step 1 Plus: QFPCR using Quantstudio 5</p>	<p>H-MDL</p>



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<p>HUMAN BODY FLUIDS / TISSUES / CELLULAR MATERIAL (cont'd)</p> <p>DNA and/or RNA from - Peripheral blood (EDTA), bone marrow (EDTA), blood (lithium heparin), blood (Sodium citrate), bone marrow (lithium heparin), Lymphocyte cell pellets in PBS, lyophilised cells</p>	<p><u>Molecular Diagnostics:</u> <u>DNA and RNA profiling for detection of abnormal sequences for clinical diagnosis (cont'd)</u></p>	<p>Documented in house methods and manufacturer's instructions for molecular diagnostics</p>	
	<p>Factor V (FVL)</p>	<p>Factor V and Prothrombin Testing Using Xpert® FII & FV Cartridges - CEL-LP-655-H</p>	H-MDL
	<p>APO E</p>	<p>Apolipoprotein-E Mutation Detection using Taqman FAST-PCR Genotyping - CEL-LP-533-H</p>	H-MDL
	<p>MPN Panel- Targeted capture of genes involved in Myeloproliferative Neoplasms</p>	<p>Illumina MiSeq: AmpliSeq for Illumina Library prep - CEL-LP-710-H v1.5</p>	H-MDL
	<p>Myeloid Panel- Targeted capture of genes involved in Myeloid Leukaemias and Myelodysplasia - detection of small sequence variation by NGS panel</p>	<p>Thermofisher Ion Chef / S5: Myeloid Oncomine Myeloid Labwork - CEL-LP-730-H v1.1, Myeloid NGS analysis using Ion reporter - CEL-LP-738-H</p>	H-MDL



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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>Electronmicroscopic 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 - CEL-LP-564-X</p> <p>Processing paraffin wax blocks for TEM - CEL-LP-583-X</p> <p>Reprocessing paraffin wax section for TEM - CEL-LP-584-X</p> <p>Followed by either:</p> <p><u>Manual sample processing:</u></p> <p>Routine Processing to Spurr Epoxy Resin - CEL-LP-576-X</p> <p>OR</p> <p><u>Automated sample processing - Leica EM TP, Lynx:</u></p> <p>Automatic processing with the Leica processor - CEL-LP-587-X</p> <p>Automatic Processing of tissue for Transmission Electron Microscopy using the Lynx Processor - CEL-LP-578-X</p>	<p>X-EM</p> <p>X-EM</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>Electronmicroscopic examinations for the purpose of clinical diagnosis (cont'd)</u>	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> - Reichert-Jung Ultracut, Ultracut E, Reichert OMU3:	
		Preparation of resin embedded tissue blocks for ultramicrotomy - CEL-LP-589-X	X-EM
		Preparation of glass knives for ultramicrotomy - CEL-LP-590-X	X-EM
		Preparation of semi-thin (thick) survey sections for light microscopy - CEL-LP-591-X	X-EM
		Preparation of ultra-thin (thin) sections for Transmission Electron Microscopy - CEL-LP-592-X	X-EM
		<u>Manual staining:</u>	
Semi-thin sections of resin embedded cells/tissue biopsies	Toluidine blue stain for overview staining	Staining semi-thin (thick) survey sections for examination by light microscopy - CEL-LP-593-X	X-EM
Ultra-thin sections of resin embedded cells/tissue biopsies		Staining ultra-thin (thin) sections with heavy metals for Transmission Electron Microscopy - CEL-LP-594-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 (cont'd)</u></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 H7650 Transmission Electron Microscope, AMT XR80 digital camera:</p>	
		<p>Operation & Maintenance of the Hitachi H7650 Transmission Electron Microscope - CEL-LP-599-X</p> <p>Digital Imaging on the Transmission Electron Microscope - CEL-LP-602-X</p> <p><u>Interpretation/Reporting:</u></p> <p>Handling and reporting surgical tissues - CEL-LP-628-X</p>	<p>X-EM</p> <p>X-EM</p> <p>X-EM</p>
<p>Bone marrow, peripheral blood, CSF</p>	<p>Cytogenetic examination for the purposes of clinical diagnosis</p> <p>Karyotyping analysis of G-banded chromosomes</p>	<p>Manual slide making for Zeiss Primo Star phase microscope: Cytogenetics sample set up CEL-LP-518-H Cytogenetics harvest CEL-LP-523-H Cytogenetics slide-making CEL-LP-525-H</p>	H-CytoG
		<p>Cytogenetics Banding - CEL-LP-463-H</p> <p>Image capture for chromosome preparations using Leica GSL120 and Leica CytoVision karyotyping stations: Use of Cytogenetic Imaging Systems CEL-LP-714-H</p>	<p>H-CytoG</p> <p>H-CytoG</p>



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HUMAN BODY TISSUES / CELLULAR MATERIAL (cont'd)	<u>Cytogenetic examination for the purposes of clinical diagnosis</u>	In-house documented methods for examination incorporating manufacturer's instructions where relevant:	
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 CEL-LP-521-H	H-CytoG
		Cytogenetics Manual FFPE FISH - CEL- LP-529-H	H-CytoG
		FISH analysis using Zeiss Axio Imager M2 and ISIS (Metasystems) software	H-CytoG
		Use of Cytogenetic Imaging Systems - CEL-LP-714-H	
Bone marrow, peripheral blood		CD138+ cell enrichment in plasma cell myeloma prior to FISH: Automated cell separation using AutoMACS Pro Miltenyi Biotech CEL-LP-703-H	H-CytoG
		Reporting and Authorisation of G-Banding and FISH Reports in Cytogenetics CEL-LP-561-H	H-CytoG
		Guidelines for the Analysis of G-Banded chromosomes and fluorescence in situ hybridisation (FISH) samples from patients with haematological neoplasms - CEL-LP-693-H	H-CytoG
END			