

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



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Accredited to
ISO 15189:2022

East Kent Hospitals University NHS Foundation Trust

Issue No: 011 Issue date: 23 May 2025

Cellular Pathology

East Kent Hospitals University NHS Foundation Trust
William Harvey Hospital
Kennington Road
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United Kingdom

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Testing performed by the Organisation at the locations specified below

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity	Location Code
Cellular Pathology East Kent Hospitals University NHS Foundation Trust William Harvey Hospital Kennington Road Willesborough Ashford Kent TN24 0LZ Local Contact Stuart Turner	Cellular Pathology	A

Site activities performed away from the locations listed above:

Location details	Activity	Location code
Kent & Canterbury Hospital Local contact Stuart Turner	Interoperative frozen sections to assist the Mohs' Micrographic Surgery Service ROSE clinic for thyroid FNA diagnostic cytology	B



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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</p> <p>Tissue: biopsy, excision, resection and post-mortem specimens</p> <p>Formalin Fixed Paraffin wax blocks of processed tissue</p> <p>Fixed fresh and frozen tissue</p> <p>Fresh Tissue</p> <p>Fixed, fresh and frozen tissue</p>	<p><u>Histopathological examination activities for the purposes 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>Examination and activities associated with decalcification of tissues</p> <p>Examination and activities associated with cutting and staining fresh tissue for rapid frozen section</p> <p>Routine morphological staining for the detection of basophilic and eosinophilic structures</p>	<p>Macroscopic and Microscopic examination using documented procedures and methods and where relevant, manufacturer's instructions</p> <p>Specimen dissection, Afos ventilated tables, Cerebro work station and SOP's CEL-LP-104, CEL-LP-494</p> <p>Tissue processing Using Leica Peloris Tissue Processor And SOP's CEL-LP-503</p> <p>Tissue Embedding Using Leica embedding stations and Cerebro workstation and SOP CEL-LP-411</p> <p>Tissue Sectioning Using Leica Rotary Microtomes RM2135, RM 2235, RM 2245, Cerebro workstation and SOP's CEL-LP-420</p> <p>Decalcification of tissues SOP's CEL LP 123, CEL LP 124, CEL LP 449 and using Qados Faxitron unit and Exact BoneSaw.</p> <p>Cryotomy Intra Operative Frozen sections using Leica cryostat CM1950 and SOP's CEL-LP-120, CEL-LP-493, CEL-LP-495.</p> <p>CEL LP 188, CEL LP 439 CEL LP 271, CEL LP 272, CEL LP 506, CEL LP 537, CEL LP 538 H&E staining using Sakura Prisma Autostainer and coverslipper and manual staining, Cerebro workstation</p>	A



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	Macroscopic and Microscopic examination using documented procedures and methods and where relevant, manufacturer's instructions	A
FFPE slides (Formalin fixed paraffin embedded) tissue on glass slides	Morphological assessment and interpretation/diagnosis	Interpretive/diagnostic microscopy SOP CEL-LP-429	
Paraffin wax sections	Special stains for the detection of: Acid and Neutral Mucins Glycogen/Neutral Mucins/Fungi	Periodic Acid Schiff with Optional Glycogen Digestion (PAS / DPAS) Schiff technique (MALLORY 1956) and Alcian Blue (AB) manual method and SOPs CEL-LP-495, CEL-LP-176, CEL-LP-515	
Paraffin wax sections	Amyloid	Highman's Congo Red (HIGHMAN 1946) and SOP CEL-LP-495	
Paraffin wax sections	Helicobacter/Microorganisms	Giemsa SOP's CEL-LP-495	
Paraffin wax sections	Elastic fibres & connective tissue	Martius Yellow – Brilliant Crystal Scarlet – Methyl Blue MSB SOP CEL-LP-495	
Paraffin wax sections	Hemosiderin, Iron	Perls Prussian Blue SOP CEL-LP-495	
Paraffin wax sections	Reticulin Fibres	Gordon and Sweets SOP CEL-LP-495	
Paraffin wax sections	Liver Reticulin	Reticulin Stain (Glees modified technique) SOP CEL-LP-495	
Paraffin wax sections	Acid Fast Bacilli	Ziehl Neelsen (Kinyuoin 1915) SOP CEL-LP-495	
Paraffin wax sections	Glycogen/Neutral Mucins/Fungi	Periodic Acid Schiff using automated Sakura TissueTEK Prisma stainer and coverslipper CEL LP 515 and CEL LP 495	
Paraffin wax sections	Pneumocystis and Fungi	Grocott technique SOP CEL-LP-495	



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented manual procedures using Leica Spectra Autostainer in conjunction with manufacturers' instructions	A
Paraffin wax sections	Connective Tissue/Collagen/Muscle	Haematoxylin Van Gieson SOP CEL-LP-495	
Paraffin wax sections	Hepatitis B Surface Antigen	Modified Orcein SOP CEL-LP-495	
Paraffin wax sections	Mast Cell Granules	Toluidine Blue Metachromatic Stain SOP CEL-LP-495	
Paraffin wax sections	Gram + & Gram – Organisms	Gram Stain SOP CEL-LP-495	
Paraffin wax sections	Elastic Fibres	EVG Elastic Van Gieson SOP CEL LP 495	
Paraffin wax sections	Immunohistochemistry to detect the following:	Documented in house methods used in accordance with Leica operating instructions for the use of Bond III automated immunostainers and SOP CEL LP 190 Incorporating the following antibodies:	
	High Molecular Weight Cytokeratin	34βE12	
	Smooth muscle actin	SMA	
	Broad range cytokeratin	AE1/AE3	
	Broad range cytokeratin	MNF116	
	Foetal Liver Cells	αFP	
	Large cell Lymphoma	ALK 1	
	Hepatocellular carcinoma	Arginase-1	
	Breat tissue and tumours	β-catenin	
	T-Cells, B-Cells in the mantle zone	BCL2	
	Follicular centre B Cells	BCL6	
	Epithelial Cells	BEREP4	
	Sialyl Lewis Antigen	CA19.9	
	Serous ovarian Carcinoma	CA125	
	Parafollicular (C-Cells)	Calcitonin	
	Actin Filament	Calponin	
	Mesothelial cell lining	Calretinin	
	Dendritic Cells and thymocytes	CD1a	
	T-Cell Marker	CD3	
	T-helper cells	CD4	
	T-Cells, B-Cells in the mantle zone	CD5	



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or equipment in conjunction with manufacturers' instructions as specified: Immunocytochemistry	A
Paraffin wax sections (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Documented in house methods used in accordance with Leica operating instructions for the use of Bond III automated immunostainers and SOP CEL LP 190 Incorporating the following antibodies:	
	T-cell mediated lymphocytic leukaemia	CD7	
	Cytotoxic T-Cells	CD8	
	Immature B Lymphocytes	CD10	
	Immature B Lymphocytes	CD15 (LEU M1)	
	B-cells marker	CD20 (L26)	
	Mature B-cells and FDC	CD21	
	FDC and EBV transformed blasts	CD23	
	RS Cells	CD30	
	Endothelial Marker	CD31, CD34	
	T-Cell and myeloid cells	CD43	
	Leukocyte common antigen	CD45 (LCA)	
	Neural cell adhesion molecule	CD56 (NCAM)	
	Megakaryocytes	CD61	
	Macrophages	CD68 KPI	
	Macrophages	CD68	
	B-cell marker	CD79α	
	Mic2 gene products	CD99	
	Mast cells and GIST	CD117	
	Plasma Cells	CD138	
	Intestinal epithelial	CDX2	
	Carcinoembryonic antigen	CEA monoclonal	
	Neuroendocrine	CHROM.A	
	Mantle cell lymphoma	Cyclin D1 (BCL1)	
	Glandular, transitional epithelia	CK7	
	Low molecular weight marker	CK8/18	
	Squamous, basal epithelia	CK14	
	Epithelial cells	CK19	
	Gastrointestinal epithelia	CK20	
	CMV infected cells	CMV	
	Lymphatic endothelium	D2-40	
	Intermediate filament	Desmin	



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods and equipment in conjunction with manufacturers' instructions as specified: Immunocytochemistry	A
Paraffin wax sections (cont'd)	Immunohistochemistry to detect the following: (cont'd) GIST Cell adhesion molecule Epithelial membrane antigen Oestrogen Receptor Fibrohistocytic Marker Gross Cystic Disease Fluid Protein Mesothelioma Melanosomes Leydig, Steroli Cells Kappa Light Chains Proliferation Marker Lambda Light Chain Melanocytes B-cells Monocytes Prostate adenocarcinoma Liver carcinoma B-cell lymphoma OCT 3/4 Seminoma mRNA/ p16 HPV marker Tumour Suppressor Gene Basal Cell Marker Prostatic Acid Phosphatase Serous and renal carcinoma Neuroendocrine marker Placental Alkaline Phosphatase Progesterone Receptor Prostate specific antigen Neoplastic prostate glands Proximal tubules Melanoma, neuroendocrine Smooth muscle myosin	Documented in house methods used in accordance with Leica operating instructions for the use of Bond III automated immunostainers and SOP CEL LP 190 Incorporating the following antibodies: DOG 1 E-Cadherin EMA ER Factor 13a GCDFP-15 HBME-1 HMB45 Inhibin KAPPA KI67 LAMBDA MELA MUM-1 MPO NKX3.1 OCH1E5 OCT 2 OCT 3/4 P16 P53 P63 PAPh PAX-8 PGP9.5 PLAP PR PSA RACEMACE (AMACR) RCC S100 SMM-HC	



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HUMAN BODY TISSUE (cont'd)	<u>Immuno histochemical examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods and equipment in conjunction with manufacturers' instructions as specified: Immunocytochemistry	A
Paraffin wax sections (cont'd)	Immunohistochemistry to detect the following (cont'd)	Documented in house methods used in accordance with Leica operating instructions for the use of Bond III automated immunostainers and SOP CEL LP 190 Incorporating the following antibodies:	
	<p>Melanoma Neuroendocrine Early B cell, thymocytes marker Lymphatic endothelia Thyroid follicles Thyroid Transcription Factor – 1 mesenchyme Marker Plasma Cell Marker Wilms tumour gene product Triple cocktail for prostate cancer Urinary Tract and prostate cancer Lung &Respiratory Cancer Mismatch Repair DNA diagnostic panel for colon cancer</p> <p>In-situ hybridisation to detect the following:</p> <p>Epstein Barr Virus</p>	<p>SOX-10 Synaptophysin TdT Thrombomodulin (CD141) Thyroglobulin TTF-1 Vimentin VS38c WT1 PDS1 Cocktail GATA3 Napsin A MMR panel (MLH-1, MSH-2, MSH-6, PMS-2)</p> <p>Documented in house methods used in accordance with Leica operating instructions for the use of Bond III automated immunostainers and SOP CEL LP 190 Incorporating the following antibodies:</p> <p>EBV (LMP1)</p>	



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<p>HUMAN BODY FLUIDS and MATERIAL</p> <p>Body Fluids (CSF, urine, general body fluids, Bronchial brushings, Washings and Sputum, Fluid Crystal Analysis, thyroid FNA)</p>	<p><u>Cytological examination activities for the purposes of clinical diagnosis</u></p> <p>Non Gynae examination activities in order to identify or exclude cytological abnormalities for the purpose of diagnosis</p>	<p>In-house documented procedures using manual methods and equipment in conjunction with manufacturers' instructions as specified:</p> <p><u>Preparation/centrifugation</u> using documented procedures CEL LP 218, CELLP 223, CEL LP 215, CEL LP 213, CEL LP 214, CEL-LP-500 CEL-LP-265 CEL-LP-472 in accordance with instructions for the operation of Thermo fisher megafuge 16 and centrifuge</p> <p><u>Staining</u> using in-house procedures for Manual May Grunwald Giemsa: CEL-LP-237, CEL-LP-613, CEL-WI-614, CEL-LP-500, LP-CEL-472, LP-CEL-038, CEL-LP-265</p> <p>Automated Papanicolaou Staining Lecia ST5020/CV5030 and procedures: CEL-LP-202, CEL-FO-680, CEL-LP-277, CEL-LP-278, CEL-LP-499, CEL-LP-463, LP-CEL-488</p>	<p>A, B</p> <p>A, B</p> <p>A</p>
<p>Slides prepared in house from samples listed above</p>	<p>Morphological assessment and interpretation/diagnosis</p>	<p>Microscopy (qualitative analysis) In-house procedure: SOP CEL-LP-429, CEL LP 330</p>	<p>A, B</p>
<p>Frozen sections</p>	<p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p>	<p>Mohs' microsurgery procedure using Leica CM1950 cryostat and SOPs CEL LP 120, CEL LP 448</p>	<p>B</p>
END			