Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

9246

Accredited to ISO 15189:2012

East Kent Hospitals University NHS Foundation Trust

Issue No: 010 **Issue date**: 03 October 2024

Cellular Pathology
East Kent Hospitals University NHS Foundation Trust
William Harvey Hospital
Kennington Road
Willesborough
Ashford
Kent
TN24 0LZ
United Kingdom

Contact: Dr Doraline Phillips
Tel: +44 (0)1233 616 604
E-Mail: doraline.phillips@nhs.net
Website: www.ekhuft.nhs.uk

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 Rd Willesborough Ashford Kent TN24 0LZ	**Local Contact** Tyler Lloyd	Cellular Pathology	A

Site activities performed away from the locations listed above:

Location details		Activity	Location code
Kent & Canterbury Hospital	**Local contact** Tyler Lloyd	Interoperative frozen sections to assist the Mohs' Micrographic Surgery Service	B

9246 Accredited to ISO 15189:2012	**Schedule of Accreditation** **issued by** **United Kingdom Accreditation Service** 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK **East Kent Hospitals University NHS Foundation Trust** **Issue No:** 010 **Issue date:** 03 October 2024
Testing performed at the above address only	

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN BODY TISSUE	Histopathological examination activities for the purposes of clinical diagnosis	Macroscopic and Microscopic examination using documented procedures and methods and where relevant, manufacturer's instructions	A
Tissue: biopsy, excision, resection and post-mortem specimens	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Specimen dissection, Afos ventillated tables, Cerebro work station and SOP's CEL-LP-104, CEL-LP-494, Tissue processing Using Leica Peloris Tissue Processor And SOP's CEL-LP-503 Tissue Embedding Using Leica embedding stations and Cerebro work station and SOP CEL-LP-411	
Formalin Fixed Paraffin wax blocks of processed tissue		Tissue Sectioning Using Leica Rotary Microtomes RM2135, RM 2235, RM 2245, Cerebro workstation and SOP's CEL-LP-420	
Fixed fresh and frozen tissue	Examination and activities associated with decalcification of tissues	Decalcification of tissues SOP's CEL LP 123, CEL LP 124, CEL LP 449 and using Qados Faxitron unit and Exact BoneSaw .	
Fresh Tissue	Examination and activities associated with cutting and staining fresh tissue for rapid frozen section	Cryotomy Intra Operative Frozen sections using Leica cryostat and SOP's CEL-LP-120, CEL-LP-493, CEL-LP-495.	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	Macroscopic and Microscopic examination using documented procedures and methods and where relevant, manufacturer's instructions	A
Fixed, fresh and frozen tissue	Routine morphological staining for the detection of basophilic and eosinophilic structures	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, Cerebro workstation	
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	HIGHMANS 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	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented manual procedures using Leica Spectra Autostainer in conjunction with manufacturers' instructions	A
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	
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	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or equipment in conjunction with manufacturers' instructions as specified: Immunocytochemistry	A
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:	
Paraffin wax sections	High Molecular Weight Cytokeratin	34βE12	
	Smooth muscle actin	SMA	
	Broad range cytokeratin	AE1/AE3, MNF116	
	Foetal Liver Cells	αFP	
	Large cell Lymphoma	ALK 1	
	Hepatocellular carcinoma	Arginase-1	
	T-Cells, B-Cells in the mantle zone	BCL2	
	Follicular centre B Cells	BCL6	
	Epithelial Cells	BEREP4	
	Sialyn Lewis Antigen	CA19.9	
	Serous ovarian Carcinoma	CA125	
	Parafollicular (C-Cells)	Calcitonin	
	Actin Fillament	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	
	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 myloid cells	CD43	
	Leukocyte common antigen	CD45 (LCA)	
	Neural cell adhesion molecule	CD56 (NCAM)	
	Macrophages	CD68 KPI	
	Macrophages	CD68	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	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:	
Paraffin wax sections (cont'd)	B-cell marker	CD79α	
	Mic2 gene products	CD99	
	Mast cells and GIST	CD117	
	Plasma Cells	CD138	
	Intestinal epithelial	CDX2	
	Carcinoembryonic antigen	CEA monoclonal	
	Carcinoembryonic antigen	CEA polyclonal	
	Neuroendocrine	CHROM.A	
	Mantle cell lymphoma	Cyclin D1 (BCL1)	
	Glandular, transitional epithelia	CK7	
	Low molecular weight marker	CK8/18	
	Sqaumous, basal epithelia	CK14	
	Epithelial cells	CK19	
	Gastrointesinal epithelia	CK20	
	Lymophatic endothelium	D2-40	
	Intermediate filament	Desmin	
	GIST	DOG 1	
	Cell adhesion molecule	E-Cadherin	
	Epithelial membrane antigen	EMA	
	Oestrogen Receptor	ER	
	Fibrohistocytic Marker	Factor 13a	
	Gross Cystic Disease Fluid Protein	GCDFP-15	
	Astrocytes,CNS	GFAP	
	Mesothelioma	HBME-1	
	Trophoblasts	HCG	
	Melanosomes	HMB45	
	Leydig, Steroli Cells	Inhibin	
	Kappa Light Chains	KAPPA	
	Proliferation Marker	KI67	
	Lambda Light Chain	LAMBDA	
	Epstein Barr Virus	LMP-1 (EBV)	
	Melanocytes	MELA	
	B-cells	MUM-1	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN BODY TISSUE (cont'd)	Immuno histochemical examination activities for the purposes of clinical diagnosis (cont'd)	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:	
Paraffin wax sections (cont'd)	Monocytes	MPO	
	Prostate adenocarcinoma	NKX3.1	
	Liver carcinoma	OCH1E5	
	B-cell lymphoma	OCT 2	
	OCT 3/4 Seminoma	OCT 3/4	
	mRNA/ p16 HPV marker	P16	
	Tumour Suppressor Gene	P53	
	Basal Cell Marker	P63	
	Prostatic Acid Phosphatase	PAPh	
	Serous and renal carcinoma	PAX-8	
	Neuroendocrine marker	PGP9.5	
	Placental Alkaline Phosphatase	PLAP	
	Progesterone Receptor	PR	
	Prostate specific antigen	PSA	
	Neoplastic prostate glands	RACEMACE (AMACR)	
	Proximal tubules	RCC	
	Melanoma, neuroendocrine	S100	
	Smooth muscle myosin	SMM-HC	
	Melanoma	SOX-10	
	Neuroendocrine	Synaptophysin	
	Early B cell, thymocytes marker	TdT	
	Lymphatic endothelia	Thrombomodulin (CD141)	
	Thyroid follicles	Thyroglobulin	
	Thyroid Transcription Factor – 1	TTF-1	
	mesenchyme Marker	Vimentin	
	Plasma Cell Marker	VS38c	
	Wilms tumour gene product	WT1	
	Triple cocktail for prostate cancer	PDS1 Cocktail	
	Urinary Tract and prostate cancer	GATA3	
	Lung &Respiratory Cancer	Napsin A	
	Mismatch Repair DNA diagnostic panel for colon cancer	MMR	

9246 Accredited to ISO 15189:2012	**Schedule of Accreditation** **issued by** **United Kingdom Accreditation Service** 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK **East Kent Hospitals University NHS Foundation Trust** **Issue No:** 010 **Issue date:** 03 October 2024
Testing performed at the above address only	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN BODY FLUIDS and MATERIAL	Cytological examination activities for the purposes of clinical diagnosis	In-house documented procedures using manual methods and equipment in conjunction with manufacturers' instructions as specified:	
Body Fluids (CSF, urine, general body fluids, Bronchial brushings, Washings and Sputum, Fluid Crystal Analysis)	Non Gynae examination activities in order to identify or exclude cytological abnormalities for the purpose of diagnosis	Prepatation/centrifugation using documented procedures CEL LP 218, CEL LP 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 Staining 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 Automated Papanicolao 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	A
Slides prepared in house from samples listed above	Morphological assessment and interpretation/diagnosis	Microscopy (qualitative analysis) In-house procedure: SOP CEL-LP-429, CEL LP 330	
Frozen sections	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Cryotomy and staining using Leica CM1950 cryostat and SOPs CEL LP 120, CEL LP 448	B
END			