


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: 003 Issue date: 08 February 2019	
	Cellular Pathology East Kent Hospitals University NHS Foundation Trust William Harvey Hospital Kennington Rd Willesborough Ashford Kent TN24 0LZ United Kingdom	Contact: Dr Nicola Chaston Tel: +44 (0)1233 616183 Fax: +44 (0) 01233 616018 E-Mail: nicola.chaston@nhs.net Website: www.ekhuft.nhs.uk
Testing performed at the above address only		

Site activities performed away from the locations listed above:

Location details	Activity	Location code
Kent and Canterbury Hospital Ethelbert Road Canterbury CT1 3NG United Kingdom	Body Store	B
C. Queen Elizabeth the Queen Mother Hospital St Peters Road Kent CT9 4AN	Mortuary	C



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis</u>	Macroscopic and Microscopic examination using documented procedures and methods and where relevant, manufacturer's instructions
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 ventilated 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.
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 H&E staining Using Leica Autostainer XL and Leica 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



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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 manual procedures using Leica Spectra Autostainer in conjunction with manufacturers' instructions
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
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 section	Elastic Fibres	EVG Elastic Van Gieson SOP CEL LP 495



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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 or equipment in conjunction with manufacturers' instructions as specified: Immunocytochemistry
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 Smooth muscle actin Broad range cytokeratin Foetal Liver Cells Large cell Lymphoma T-Cells, B-Cells in the mantle zone Follicular centre B Cells Epithelial Cells Sialyn Lewis Antigen Serous ovarian Carcinoma Parafollicular (C-Cells) Actin Filament Mesothelial cell lining Dendritic Cells and thymocytes T-Cell Marker T-helper cells T-Cells, B-Cells in the mantle zone Cytotoxic T-Cells Immature B Lymphocytes Immature B Lymphocytes B-cells marker Mature B-cells and FDC FDC and EBV transformed blasts RS Cells Endothelial Marker T-Cell and myloid cells Leukocyte common antigen Neural cell adhesion molecule Macrophages Macrophages B-cell marker Mic2 gene products	34βE12 SMA AE1/AE3, MNF116 αFP ALK 1 BCL2 BCL6 BEREP4 CA19.9 CA125 Calcitonin Calponin Calretinin CD1a CD3 CD4 CD5 CD8 CD10 CD15 (LEU M1) CD20 (L26) CD21 CD23 CD30 CD31, CD34 CD43 CD45 (LCA) CD56 (NCAM) CD68 KPI CD68 CD79α CD99



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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
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	Mast cells and GIST Plasma Cells Intestinal epithelial Carcinoembryonic antigen Carcinoembryonic antigen Neuroendocrine Mantle cell lymphoma Glandular, transitional epithelia Low molecular weight marker Squamous, basal epithelia Epithelial cells Gastrointestinal epithelia Lymphatic endothelium Intermediate filament GIST Cell adhesion molecule Epithelial membrane antigen Oestrogen Receptor Fibrohistocytic Marker Gross Cystic Disease Fluid Protein Astrocytes,CNS Mesothelioma Trophoblasts Melanosomes Leydig, Steroli Cells Kappa Light Chains Proliferation Marker Lambda Light Chain Epstein Barr Virus Melanocytes B-cells Monocytes Liver carcinoma OCT 3/4 Seminoma	CD117 CD138 CDX2 CEA monoclonal CEA polyclonal CHROM.A Cyclin D1 (BCL1) CK7 CK8/18 CK14 CK19 CK20 D2-40 Desmin DOG 1 E-Cadherin EMA ER Factor 13a GCDFP-15 GFAP HBME-1 HCG HMB45 Inhibin KAPPA KI67 LAMBDA LMP-1 (EBV) MELA MUM-1 MPO OCH1E5 OCT 3/4



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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
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	mRNA/ p16 HPV marker Tumour Suppressor Gene Basal Cell Marker Prostatic Acid Phosphatase Neuroendocrine marker Placental Alkaline Phosphatase Progesterone Receptor Prostate specific antigen Neoplastic prostate glands Proximal tubules Melanoma, neuroendocrine 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	P16 P53 P63 PAPh PGP9.5 PLAP PR PSA RACEMACE (AMACR) RCC S100 Synaptophysin TdT Thrombomodulin (CD141) Thyroglobulin TTF-1 Vimentin VS38c WT1 PDS1 Cocktail



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<p>HUMAN BODY Fluids and Material</p> <p>Cervical Cellular Material</p> <p>Liquid based Cervical cell samples</p> <p>Slides prepared in house</p>	<p><u>Cytological examination activities for the purposes of clinical diagnosis</u></p> <p>Cervical Cytology examination activities for the purposes of clinical diagnosis</p> <p>Staining of samples in order to identify or exclude cytological abnormalities for the purpose of diagnosis</p> <p>Cervical screening. Examination of samples in order to identify or exclude cytological abnormalities for the purpose of diagnosis</p> <p>Morphological assessment and interpretation/diagnosis</p>	<p>In-house documented procedures using manual methods and equipment in conjunction with manufacturers' instructions as specified:</p> <p>Documented procedures CEL LP 450, CEL LP 499, CEL LP 294 CEL LP 488 In conjunction with manufacturer's instructions for the operation of the T5000 (Hologic)</p> <p>Documented in house methods used in accordance with Leica operating instructions for the use of Leica ST5020/CV5030 Autostainer and SOP CEL LP 202, CEL LP 463, CEL LP 488 and Papanicolaou Staining</p> <p>Manual microscopy and SOP's CEL-LP-204, CEL-LP-445, CEL-LP-456, CEL-LP-475, CEL-LP-476, CEL-LP-477, CEL-LP-485, CEL-LP-486, CEL-LP-487, CEL-LP-490,CEL-LP-275, CEL-LP-280</p> <p>In house procedure CEL LP 455</p>



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<p>HUMAN BODY Fluids and Material (cont'd)</p> <p>Body Fluids (CSF, urine, general body fluids, Bronchial brushings, Washings and Sputum, Fluid Crystal Analysis)</p> <p>Slides prepared in house from samples listed above</p>	<p><u>Cytological examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Non Gynae examination activities in order to identify or exclude cytological abnormalities for the purpose of diagnosis</p> <p>Gynae examination activities in order to identify or exclude cytological abnormalities for the purpose of diagnosis</p> <p>Morphological assessment and interpretation/diagnosis</p>	<p>In-house documented procedures using manual methods and equipment in conjunction with manufacturers' instructions as specified:</p> <p>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</p> <p>Documented in house methods used in accordance with Leica operating instructions for the use of Leica ST5020/CV5030 Autostainer (Automated Papanicolaou Staining) and SOP's CEL LP 202, CEL LP 463, manual staining (MGG) CEL LP 237</p> <p>Microscopy (qualitative analysis) In-house procedure: SOP CEL-LP-429, CEL LP 330</p>
END		