


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 27661 Accredited to ISO 15189: 2012	East Suffolk and North Essex NHS Foundation Trust	
	Issue No: 001 Issue date: 27 October 2024	
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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
HUMAN BODY TISSUE Fresh & formalin fixed human tissue specimens	<u>Histopathology</u> Specimen dissection and decalcification/softening Recording of description, observations, dimensional measurement, weight	In house documented procedures using manual methods or analysers in conjunction with manufacturer's instructions for the following methods (where relevant): Equipment: Leica IPC Cassette printer Vodex downdraft benches Vodex extracted sample storage unit Clinisys Winpath LIMS Balance Steel ruler Measurement principle: Dissection of formalin fixed tissues for histological processing SOP: CELL-COL-LP-16 Cut-Up Guidelines CELL-COL-LP-18 Pathologist Cut-Up Guidelines CELL-COL-LP-6 Decalcification and Softening



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HUMAN BODY TISSUE (cont'd)	<u>Histopathology</u> (cont'd)	In house documented procedures using manual methods or analysers in conjunction with manufacturer's instructions for the following methods (where relevant):
Formalin fixed paraffin embedded tissue	Embedding of processed human tissue samples	Equipment: Sakura Tissue-Tek TEC 6 EM E2 Embedding Module Sakura Tissue-Tek TEC 6-EM-E2 Cryo Unit Measurement principle: Embedding paraffin wax processed tissue into blocks for section cutting SOP: CELL-COL-LP-3 Embedding
Formalin fixed human tissue	Routine paraffin wax tissue processing	Equipment: Sakura VIP6 AI tissue processors Measurement principle: Processing formalin fixed tissue blocks through to paraffin wax. SOP: CELL-COL-LP-7 Tissue Processing
Formalin fixed paraffin embedded human tissue blocks	Microtomy of formalin fixed paraffin embedded tissue (FFPE) samples	Equipment: Leica RM2235 / HistoCore Microtomes Gordiankey Slidebel duo slide labelling printer Section floatation baths Slide drying racks Slide drying oven SOP: CELL-COL-LP-9 Section Cutting



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HUMAN BODY TISSUE (cont'd)	<u>Histopathology</u> (cont'd)	In house documented procedures using manual methods or analysers in conjunction with manufacturer's instructions for the following methods (where relevant):
Fresh human tissue specimens	Frozen section cutting of human tissue for rapid H&E staining (cryotomy) Recording of description, observations, dimensional measurement	Equipment: Leica CM1860 UV cryostat Balance Safety Cabinet Steel Ruler Measurement principle: Dissection of fresh tissues for freezing SOP: CELL-COL-LP-11 Frozen Sections
Formalin fixed paraffin embedded tissue slides	Routine staining and coverslipping of Histology slides Review of stained slides used in the microscopic assessment and diagnosis of disease. Basophilic and eosinophilic structures – Haematoxylin & Eosin (H&E) staining of FFPE human tissue	Equipment: Leica HistoCore Spectra ST automated stainer and integrated HistoCore Spectra CV coverslipper. Measurement principle: Haematoxylin and Eosin staining of human tissue sections on glass slides. SOP: CELL-COL-LP-2 Haematoxylin and Eosin (Including Automated Staining and Coverslipping Machines)



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HUMAN BODY TISSUE (cont'd) Formalin fixed paraffin embedded tissue slides and Frozen tissue slides (rapid H&E for frozen section only)	<u>Histopathology</u> (cont'd) Special staining & coverslipping of FFPE tissue (fresh frozen tissue for frozen section) histology slides Review of stained slides used in the microscopic assessment and diagnosis of disease Acid fast bacilli including Tubercle bacilli - AFB (Acid fast bacilli) Acid mucins - Alcian blue Acid and neutral mucins - Alcian blue periodic acid Schiff +/- digestion Amyloid - Congo red Elastic fibres - Elastic Van Gieson Gram +ve and -ve bacteria - Gram Fungi and Pneumocystis - Grocott Collagen - Haematoxylin Van Gieson Muscle, collagen - Masson Trichrome Copper-associated protein, hepatitis B surface antigen - Orcein Fungi, glycogen, mucins - Periodic acid schiff +/- digestion Ferric iron, asbestos - Perls Reticulin fibres - Reticulin silver Basophilic and eosinophilic structures - Rapid H&E for frozen section	In house documented procedures using manual methods or analysers in conjunction with manufacturer's instructions for the following methods (where relevant): Equipment: Vodex downdraft bench Oven Water bath Leica HistoCore Spectra ST automated stainer and integrated HistoCore Spectra CV coverslipper Measurement principle: Special staining/Rapid H&E staining of human tissue sections on glass slides SOP: CELL-COL-LP-12 Acid Fast Bacilli CELL-COL-LP-13 Alcian blue CELL-COL-LP-14 Alcian blue periodic acid Schiffs CELL-COL-LP-4 Congo red CELL-COL-LP-8 Elastic Van Gieson CELL-COL-LP-17 Gram CELL-COL-LP-21 Grocott CELL-COL-LP-15 Haematoxylin van Gieson CELL-COL-LP-26 Masson Trichrome CELL-COL-LP-22 Orcein CELL-COL-LP-23 Periodic Acid Schiff CELL-COL-LP-24 Perls Pussian Blue CELL-COL-LP-25 Reticulin Silver CELL-COL-LP-11 Frozen Section



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HUMAN BODY TISSUE (cont'd)	<u>Histopathology</u> (cont'd)	In house documented procedures using manual methods or analysers in conjunction with manufacturer's instructions for the following methods (where relevant):
Formalin fixed paraffin embedded tissue slides	Immunohistochemistry staining & coverslipping of FFPE tissue histology slides: Qualitative immunohistochemical detection of: 34βE12 (HMWCK) ACTIN (SMA) AE1/AE3 ALPHA FETOPROTEIN (AFP) AMACR (P504s/RACEMASE) BCL2 BCL6 BerEP4 CA125 CALRETININ CAM 5.2 CD3 CD5 CD10 CD15 CD20 CD23 CD30 CD31 CD34 CD45 (LCA) CD56 CD68 CD79A CD117 CD138 CDX2 CEA MONO CHROMOGRANIN A CK5/6 CK 7 CK14 CK20 CMV CYCLIN D1	Equipment: Ventana Benchmark ULTRA Slide drying oven Leica HistoCore Spectra ST automated stainer and integrated Leica HistoCore Spectra CV Coverslipper Measurement principle: Immunohistochemistry staining of human tissue sections on glass slides SOP: CELL-COL-LP-5 Immunohistochemistry



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HUMAN BODY TISSUE (cont'd) Formalin fixed paraffin embedded tissue slides (cont'd)	<u>Histopathology</u> (cont'd) Immunohistochemistry staining & coverslipping of FFPE tissue histology slides: Qualitative immunohistochemical detection of: (cont'd) D2-40 DESMIN DOG 1 E-CADHERIN EMA ER GATA3 HCG HELICOBACTER PYLORI HEP PAR-1 HMB45 KI67 MELAN A MUM-1 OCT3/4 p16 p40 p53 p63 PAX8 PLAP PR PSA S100 SMM SYNAPTOPHYSIN TTF-1 VIMENTIN WT1	In house documented procedures using manual methods or analysers in conjunction with manufacturer's instructions for the following methods (where relevant): Equipment: Ventana Benchmark ULTRA Slide drying oven Leica HistoCore Spectra ST automated stainer and integrated Leica HistoCore Spectra CV Coverslipper Measurement principle: Immunohistochemistry staining of human tissue sections on glass slides SOP: CELL-COL-LP-5 Immunohistochemistry



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HUMAN BODY TISSUE (cont'd) Stained histology slides from FFPE and frozen tissue Stained diagnostic cytology slides Fresh human synovial fluid samples	<u>Histopathology</u> (cont'd) Review of stained slides used in the microscopic assessment and diagnosis of disease Recording of description, observations, dimensional measurement and semi-quantitative scoring Diagnostic cytology Preparation of synovial fluids for identification of crystals Screening of wet preparations of synovial fluid samples using polarising microscopy for: Urate (monosodium urate monohydrate) CPPD (Calcium pyrophosphate dehydrate)	In house documented procedures using manual methods or analysers in conjunction with manufacturer's instructions for the following methods (where relevant): Equipment: Clinisys WinPath LIMS Microscopes Measurement principle: Microscopic review of slides SOP: CELL-COL-GP-38 Pathologist reporting and Authorisation of Reports Equipment: Polarising microscope Safety cabinet Downdraft bench Measurement principle: Creation of synovial fluid wet preparations on glass slides SOP: CELL-COL-LP-27 synovial fluid for crystals
END		