


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 9402 Accredited to ISO 15189:2012	Royal United Hospitals Bath NHS Foundation Trust	
	Issue No: 004 Issue date: 10 December 2019	
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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
Address Department of Histopathology Royal United Hospitals NHS Foundation Trust Combe Park Bath BA1 3NG	Local contact Kyle Day Tel: +44 (0) 1225 821770
	Routine Histopathology Special Stains Immunohistochemistry Diagnostic non-gynae cytology Interpretation and reporting Intra-operative frozen sections Mortuary services (body receipt, storage and release)

Site activities performed away from the locations listed above:

Location details	Activity
Royal United Hospitals NHS Foundation Trust Combe Park Bath BA1 3NG	Archives Storage of records only



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY TISSUE</p> <p>Tissue Samples: Fixed, fresh and frozen tissue; excisional and incisional biopsies and surgical resection specimens</p> <p>Formalin Fixed Paraffin wax blocks of processed tissue</p> <p>Fresh Tissue</p>	<p><u>Histological examination activities for the purposes of clinical diagnosis</u></p> <p>Routine Histopathology examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Macroanalysis and dissection using documented in house procedure Technical cut-up - HI-170 Specimen Dissection - HI-182</p> <p>Decalcification using documented in house procedure HI-337</p> <p>Processing Using: Thermofisher Excelsior Processors - HI-229</p> <p>Embedding Using: Tissue Tek 5 Embedding Centres - HI-156</p> <p>Sectioning Using: Leica Rotary Microtomes models RM2235 (5) and RM2245 - HI-167</p> <p>Cryotomy intra-operative frozen sections Using: Leica C1850 and C1750 cryostats HI-128 HI-304 HI-11 HI-223</p>



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HUMAN BODY TISSUE (cont'd)	<u>Histological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
Formalin fixed paraffin embedded (FFPE) and frozen section slides	Routine morphological staining for the detection of: Basophilic and eosinophilic tissue structures	Routine Haematoxylin and Eosin (H&E) staining Automated using: Thermofisher Gemini AS Stainer - HI-162 & 163 and Thermofisher Clearvue Coverslipper – HI-311 Manual: H&E staining – HI-78 Frozen section staining (Manual H&E) - HI-11
FFPE sections	Special stains to detect the following: Acid mucins Acid mucins, alkaline mucins Amyloid Elastic Fibres Granular inclusions Helicobacter Pylori Demonstration of fungi Gram positive and gram negative bacteria Connective Tissues Melanin Muscle and Collagen Basement Membranes	Manual special staining techniques using documented in house procedures for staining with: Alcian Blue Periodic Acid Schiff's Stain – HI-48 Alcian Blue Periodic Acid Schiff's Stain with Diastase – HI-49 Congo Red – HI-63 Elastin van Gieson – HI-70 Giemsa – HI-74 Giemsa method for Helicobacter – HI-75 Grocott's Modification of Gomori's Methenamine Silver - SOP-HI-77 Hucker Conn/Twort – HI 82 Martius Scarlet Blue – HI-90 Masson Fontana – HI-91 Masson Trichrome – HI-92 Methenamine silver for basement membranes – HI-94



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HUMAN BODY TISSUE (cont'd)	<u>Histological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE sections (cont'd)	Special stains to detect the following: (cont'd)	Manual special staining techniques using documented in house procedures for staining with:
FFPE and Frozen sections	Lipid	Oil Red O – HI-99
	Iron	Perls Prussian Blue – HI-102
	Glycogen/mucin	Periodic Acid Schiff – HI-103
	Reticulin Fibres	Reticulin stain – modified Gomori – HI-106
	Copper	Rhodanine – HI-107
	Metachromasia (mast cells, cartilage matrix, some connective tissue, mucopolysaccharides)	Toluidine Blue for Metachromasia – HI-108
	Copper associated protein	Rubeanic Acid – HI-110
	Calcium	Von Kossa – HI-112
	Hepatitis B	Shikata's Orcein – HI-114
	Amyloid	Sirius Red – HI-116
	Epithelial mucin	Southgates Mucicarmine – HI-118
	Tubercule bacilli	Ziehl Neelsen – HI-122
	Nuclei collagen and muscle	Van Gieson
	Helicobacter and Spirochaetes	Warthin and Starry – HI-126
	M.leprae and other mycobacteria	Wade Fite – HI-125



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>FFPE sections</p>	<p><u>Histological examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Immunohistochemistry to detect the following:</p> <p>Pan-cytokeratin - cytoplasmic</p> <p>Normal Epithelia - cytoplasmic</p> <p>Small B lymphocytes in the mantle and marginal zones and many T cells – cytoplasmic to demonstrate follicular lymphomas</p> <p>High expression in B-lymphoid lineage cells. Present in germinal centres, B cell lymphomas</p> <p>All epithelia except the superficial layers of squamous epithelia</p> <p>Mucinous adenocarcinomas of ovary, breast, colon and lung</p> <p>Smooth muscle and myoepithelial cells</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Immunohistochemistry using documented in-house procedures:</p> <p>HI-307 SOP/HI/24 HI-19 HI-21 HI-26 HI-27 HI-29</p> <p>in conjunction with manufacturer's instructions for: Dako PT Links Dako Omnis</p> <p>AE1/3</p> <p>34 BE12</p> <p>BCI-2</p> <p>BCL-6</p> <p>Ber EP4</p> <p>CA 125</p> <p>Caldesmon</p>



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HUMAN BODY TISSUE (cont'd)	<u>Histological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE sections (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Immunohistochemistry using documented in-house procedures:
	Smooth muscle and myoepithelial cells	HI-307 SOP/HI/24 HI-19 HI-21 HI-26 HI-27 HI-29 in conjunction with manufacturer's instructions for: Dako PT Links Dako Omnis
	Mesothelial cells	Calponin
	Normal secretory epithelium	Calretinin
	T cells	CAM 5.2
	T cells, some B cell lymphomas	CD3
	Immature B and T cell precursors and proliferating B cells	CD5
	Mature granulocytes and monocytes, Reed-Sternberg cells	CD10
	B cells	CD15
	B cells follicular dendritic cells	CD20
	Follicular dendritic cells. Some B cell lymphomas	CD21
	Hodgkins/Reed-Sternberg cells	CD23
		CD30



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HUMAN BODY TISSUE (cont'd)	<u>Histological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE sections (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Immunohistochemistry using documented in-house procedures:
		HI-307 SOP/HI/24 HI-19 HI-21 HI-26 HI-27 HI-29
		in conjunction with manufacturer's instructions for: Dako PT Links Dako Omnis
	Endothelium	CD31
	Endothelium	CD34
	Leukocytes	CD45
	Neuroendocrine cells, some use in lymphoma pathology	CD56
	Macrophages	CD68
	B cells	CD79a
	Plasma cells	CD138
	GI tract mucosa, adenocarcinomas and carcinoids of the GI tract	CDX2
	Secretory granules of neuroendocrine cells	Chromogranin
	Mesothelial cells	CK5/6
	CK7 usually used as a panel to identify primary site of carcinomas	CK7



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>FFPE sections (cont'd)</p>	<p><u>Histological examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Immunohistochemistry to detect the following: (cont'd)</p> <p>CK20 usually used as a panel to identify primary site of carcinomas</p> <p>Lymphoma diagnosis</p> <p>Mantle cell lymphoma</p> <p>Skeletal, cardiac and smooth muscle</p> <p>Normal/neoplastic epithelial</p> <p>Dendritic cells, dermatofibromas</p> <p>Glandular and ductal cells of normal breast, primary and metastatic breast carcinoma</p> <p>Trophoblastic cells</p> <p>Activated melanocytes, some melanomas</p> <p>Kappa-expressing lymphocytes</p> <p>Proliferating cells</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Immunohistochemistry using documented in-house procedures:</p> <p>HI-307 SOP/HI/24 HI-19 HI-21 HI-26 HI-27 HI-29</p> <p>in conjunction with manufacturer's instructions for: Dako PT Links Dako Omnis</p> <p>CK20</p> <p>C-myc</p> <p>Cyclin D1</p> <p>Desmin</p> <p>EMA</p> <p>Factor 13a</p> <p>GCDFP-15</p> <p>hCG</p> <p>HMB45</p> <p>Kappa</p> <p>Ki67</p>



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FFPE sections (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Immunohistochemistry using documented in-house procedures:
	Lambda-expressing lymphocytes	HI-307 SOP/HI/24 HI-19 HI-21 HI-26 HI-27 HI-29 in conjunction with manufacturer's instructions for: Dako PT Links Dako Omnis
	Melanocytes, melanomas	Lambda
	Pan cytokeratin	MART-1
	Some B cell lymphomas/classical Hogkin's lymphoma.	MNF116
	P53 mutated tumours	MUM1
	Basal epithelial cells	P53
	Germ cell tumours	P63
	Benign and malignant prostate	PLAP
	Most prostate carcinomas	PSA
	Neurons, fat cells, melanocytes	Racemase (AMACR)
	Smooth muscle	S100
	Neurons, neuroendocrine cells	SMA
		Synaptophysin



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HUMAN BODY TISSUE (cont'd)	<u>Histological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE sections (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Immunohistochemistry using documented in-house procedures: HI-307 SOP/HI/24 HI-19 HI-21 HI-26 HI-27 HI-29 in conjunction with manufacturer's instructions for: Dako PT Links Dako Omnis
	Thyroid, lung carcinomas	TTF-1
	Widespread intermediate filament	Vimentin
	Ovarian adenocarcinomas, Wilm's tumour, malignant mesotheliomas	WT1
	Breast hormone receptor expression	Oestrogen receptor
	Breast hormone receptor expression	Progesterone receptor
Histological sections prepared in house as above	Morphological assessment and interpretation/diagnosis	Interpretive microscopy (qualitative analysis) using in house procedures and in accordance with manufacturers' instructions for microscopes: Leica DM4000, Leica DMRBE and Olympus BX43 HI-168 Histology Quality Control HI-188 Reporting Results HI-193 Internal Referrals HI-320 Intradepartmental Consultation



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>Human non-gynaecological fluids</p> <p>Cytological sections prepared in house from samples listed above</p>	<p><u>Non-gynaecological cytology examination activities for the purposes of clinical diagnosis:</u></p> <p>Examination of basic cellular components in order to identify or exclude morphological and cytological abnormalities</p> <p>Demonstration of : Cells (nuclei and cytoplasm) and micro organisms</p> <p>Morphological assessment and interpretation/diagnosis</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Sample preparation and processing using procedures: CY-34 CY-107 CY-156 in conjunction with manufacturer's instructions using: Cytospin 4 - CY-25 Centrifuge - CY-12</p> <p>Staining Using in-house procedures: CY-34 Papanicolaou – CY-33 May Grunwald Giemsa – CY-33 In conjunction with manufacturer's instructions using: Thermofisher Gemini Stainer - CY-33 Sakura – coverslipper - CY-158</p> <p>Interpretive microscopy (Qualitative analysis) Using in house procedures: CY-112 In conjunction with manufacturer's instructions for: Leica DMLB, Olympus BX45 and Nikon Eclipse Microscopes</p>



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Seminal Fluid (Fertility investigation)	<u>Andrology examination activities for the purposes of clinical diagnosis</u> Semen analysis: Volume Concentration Motility Number Vitality Morphology	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified based on WHO Laboratory Manual 5 th Edition (2010): Manual methods and documented in house procedures using: Centrifuge and Leica DM2000 microscope with heated stage CY-60, 61, 94, 99
Seminal fluid (post vasectomy)	Semen analysis: Absence / presence of sperm Motility	Manual method using documented in house procedures using: Centrifuge, counting chamber, Leica DM2000 microscope with heated stage CY-138
END		