Schedule of Accreditation

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United Kingdom Accreditation Service

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9039 **Accredited to ISO 15189:2012**	**West Hertfordshire Teaching Hospitals NHS Trust** **Issue No:** 007 **Issue date**: 29 November 2023	
	Histopathology **Hemel Hempstead Hospital** **Hillfield Road** **Hemel Hempstead** **Hertfordshire** **HP2 4AD** **United Kingdom**	**Contact: Wendy Riddle** **Tel: +44 (0)1442 287833** **E-Mail: wriddle@nhs.net**

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**
Address Cellular Pathology Hemel Hempstead Hospital Hillfield Road Hemel Hempstead Hertfordshire HP2 4AD United Kingdom	**Local contact** Wendy Riddle	Histopathology Immunocytochemistry Andrology- Fertility semen analysis Non-Gynae Cytology	HHH

Site activities performed away from the locations listed above:

Location details		**Activity**	**Location code**
EBUS/ EUS, Endoscopy, Level 3 PMOK Watford General Hospital Vicarage Road Watford Hertfordshire WD18 0HB	Winnie Tang (Contact details above)	Sample preparation, slide production, staining & mounting of fine needle aspirates with ROSE (Rapid On-Site Evaluation) by light microscopy of preparation for adequacy, for diagnostic cytology	WAT
Slide Store 0.06 ground floor Pathology Block Watford General Hospital	Winnie Tang (Contact details above)	Slide storage	WAT
ROSE for the Head & Neck Clinic Radiology, Jubilee Wing Hemel Hempstead Hospital Hillfield Rd Hemel Hempstead HP2 4A	Winnie Tang (Contact details above)	Sample preparation, slide production, staining & mounting of fine needle aspirates with ROSE (Rapid On-Site Evaluation) by light microscopy of preparation for adequacy, for diagnostic cytology	HHH

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES	Histopathological examination activities for the purposes of clinical diagnosis Routine Histopathology		
Fixed, fresh and frozen tissue; excisional and incisional biopsies and surgical resection specimens	Examination of tissues to identify or exclude morphological and cytological abnormalities for the purpose of clinical diagnosis	Macroscopic and Microscopic examination In-house documented procedures in conjunction with equipment as specified:	HHH
Fresh and formalin fixed human tissue specimens		Macroscopic examination In house documented procedures HISOPSD001 to HISOPSD066	HHH
Formalin fixed tissue		Tissue Processing Documented in-house procedure HISOPGL012, 080, 079 and in conjunction with manufacturer's instructions for & ASP300S, Pearl and Logos Tissue processors	HHH
Formalin fixed tissue		Embedding Documented in-house procedure HISOPGL022 in conjunction with manufacturer's instructions for Sakura Tek6 7 Myr embedding centres	HHH
Paraffin wax impregnated blocks		Microtomy Documented in-house procedure HISOPG024 in conjunction with manufacturer's instructions for Thermo Microm & Leica RM300 microtomes and Leica Cognitive printers	HHH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)		
	Routine Staining		
Paraffin wax tissue sections	Identification of basophilic & eosinophilic structures	Automated H&E staining Documented in-house procedure HISOPG029 in conjunction with manufacturer's instructions for Sakura Prisma DRS staining machine & coverslipper	HHH
	Special Staining		
Paraffin wax tissue sections & cell blocks	Examination of tissues to identify or exclude morphological and cytological abnormalities for the purpose of clinical diagnosis	Documented in-house procedures and using manual staining methods:	HHH
	Acid & neutral mucins	AB PAS/DPAS (HISOPSS001)	
	Amyloid	Congo Red (HISOPSS029)	
	Venous invasion	Elastic H&E (HISOPSS033)	
	Elastic	EVG (HISOPSS006)	
	Reticulin	Gordon & Sweets (HISOPSS010)	
	Gram +/- organisms	Gram (HISOPSS009)	
	Fungi & pneumocystis	Grocott (HISOPSS012)	
	Connective tissue	HVG (HISOPSS01)	
	Melanin	Masson Fontana (HISOPSS020)	
	Connective tissue	Masson trichrome (HISOPSS021	
	Fibrin	MSB (HISOPSS019)	
	Hepatitis B / CAP	Orcein (HISOPSS024)	
	Glycogen & PAS+ve substances	PAS/DPAS (HISOPSS025)	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	Documented in-house procedures	
	Special Staining (cont'd)	Manual staining methods (Cont'd)	
	Haemosiderin	Perls (HISOP026)	
	Calcium	Von Kossa (HISSOPSS054)	
	Leprosy bacilli	Wade Fite (HISOPSS028)	
	Tubercle bacilli	ZN (HISOPSS030)	
	Immunocytochemistry		
Paraffin wax tissue sections & cell blocks	Examination of tissues to identify or exclude morphological and cytological abnormalities for the purpose of clinical diagnosis	Documented in-house procedures HISOPIM020 in conjunction with manufacturer's instructions for antibodies, Leica Bond-III	HHH
	Epithelial cells	AE1/AE3	
	Hepatocytes & germ cell tumour	A fetoprotein	
	Muscle	ASMA	
	Scattered T cells in germinal centres & mantle zone B cells	BCL2	
	Classification of Burkitts lymphoma	BCL6	
	Mesothelioma panel marker-epithelial	BEREP4	
	Classification of adenocarcinomas especially ovarian tumours	CA125	
	Renal Cell Carcinoma	CAIX	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	Documented in-house procedures	
	Immunocytochemistry (cont'd)	Leica Bond-III using HISOPIM020 and antibodies:	
	Mesothelial cells	Calretinin	
	T cells in mantle zone	CD3	
	Thymocytes & T helper cells	CD4	
	T & B cell malignancies	CD5	
	Cytotoxic suppressor T cells	CD8	
	Burkitts' & follicular lymphoma, ALL	CD10	
	Reed Sternberg cells, Hodgkins	CD15	
	B cells / lymphoma	CD20	
	B cells / dendritic marker	CD21	
	Dendritic marker	CD23	
	Hodgkin's lymphoma	CD30	
	Endothelial marker	CD31	
	Endothelial marker	CD34	
	Lymphoma	CD45	
	Neuroendocrine tissue, carcinoid	CD56	
	Activated platelets, neutrophils & basophils	CD68	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	Documented in-house procedures	
	Immunocytochemistry (cont'd)	Leica Bond-III using HISOPIM020 and antibodies:	
	Mononuclear phagocytes, Macrophages	CD79a	
	GIST tumours	CD117	
	Plasma cells, B lymphocyte differentiation	CD138	
	Colorectal cancer	CDX-2	
	Epithelial	CEA(M)	
	Neuroendocrine cells	Chromogranin	
	Prostate/breast – differentiate between benign/malignant	CK5/6	
	Bowel	CK7	
	Epithelium	CK8/18	
	Ductal & glandular epithelium	CK19	
	Ovarian	CK20	
	Cytomegalovirus	CMV	
	Mantle cell lymphoma	Cyclin D1	
	Vascular	D240	
	Smooth & striated muscle	Desmin	
	GIST tumours	DOG-1	
	Breast E-cadherin positive cells I normal & neoplastic tissues	E-Cadherin	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	Documented in-house procedures	
	Immunocytochemistry (cont'd)	Leica Bond-III using HISOPIM020 and antibodies:	
	Epithelial cells	EMA	
	Endothelial cells & megakaryocytes	Factor FVIII	
	Breast gland	GCDFP-15	
	Breast carcinoma	GATA3	
	Yolk sac tumour	Glypican 3	
	Germ cell tumours	HCG	
	HER2 gene amplification	HER2	
	Melanocytes	HMB45	
	Mismatch repair proteins/ microsatellite instability	HNPCC (hMLH1, hMSH2, hMSH6, PMS2)	
	Sex cord stromal tumours	Inhibin	
	Light chains	Kappa	
	Proliferating cells	Ki67	
	Light chains	Lambda	
	Melanocytes, melanoma	MelanA	
	Epithelial	MNF116	
	Respiratory	MOC31	
	Ovarian & endometrial carcinoma	Napsin	
	Peripheral nerves	Neurofilament	
	Neuroendocrine	NSE	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	Documented in-house procedures	
	Immunocytochemistry (cont'd)	Leica Bond-III using HISOPIM020 and antibodies:	
	Germ cell tumours	OCT3/4	
	Breast	OR	
	Cervical Ca/Oral Ca -tumour suppressor gene	P16	
	Lung squamous cell carcinoma	P40	
	Identification of p53 in normal and neoplastic tissue	P53	
	Prostate/breast basal cells	P63	
	Renal	PAX2	
	Serous carcinoma	PAX8	
	Germ cell	PLAP	
	Breast	Progesterone	
	Prostatic epithelium	PSA	
	Prostate	Racemase	
	Renal cell carcinoma	RCC	
	Melanoma, glial cells	S100	
	Soft tissue	SMMHC	
	Melanoma	SOX10	
	Neuroendocrine	Synaptophysin	
	Thyroid transcription factor	TTF1	
	Wilms tumour	WT1	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	Documented in-house procedures	
	Immunocytochemistry (cont'd)	Leica Bond-III using HISOPIM020 and antibodies:	
	Intermediate filament protein expressed in mesochymal cells	Vimentin	
HUMAN BODY FLUIDS	Andrological examination activities for the purposes of clinical diagnosis		
Semen	Fertility testing:	Based on WHO laboratory manual for the examination and processing of human semen (Sixth edition 2021) and manual method / documented in-house procedure HISOPSA002	HHH
	Volume	Volume/weight	
	pH	Colorimetric strips	
	Sperm morphology excluding TZI scoring	Stained slides (Papanicolau) microscopy (Bright field)	
	Sperm concentration	Improved Neubauer counting chambers and Microscopy (Phase contrast)	
	Sperm motility	Microscopy (Phase contrast)	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	Diagnostic cytopathology	In-house documented procedures in conjunction with manufacturer's instructions using:	HHH
Fixed and fresh cellular material and body fluid samples, prepared slides, lymph node surgical specimens, fine needle aspirates and brushings:	Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis		
Bronchioalveolar lavages and tracheal aspirates Biliary brushings Gastric and oesophageal brushings CSF Non gynae LBC samples Breast cyst fluid FNA Serous fluids Skin scrapings Sputum Synovial fluids Urines Intraoperative lymph node		Preparation of cell samples Thermo Scientific Sorvall ST16 Centrifuge ThermoShandon Cytospin CYSOP135	HHH
		Production of cell block CYSOP027	HHH
		Production of slides for immunocytochemistry CYSOP027	HHH
		Production of slides for special stains CYSOP027	HHH
EBUS/ EUS Fine needle aspirates from: Thoracic: lung, lymph node, mediastinal and pleural Pancreatic Adrenal Head & Neck		Preparation of samples and ROSE examination of samples for adequacy prior to submission to laboratory Documented in-house procedure using DiffQuik stain and light microscopy CYSOP208	WAT/ HHH

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Diagnostic cytopathology (cont'd)	Preparation of samples Documented in-house procedures CYSOP175, CYSOP132	HHH
Fine needle aspirates from: Lymph nodes Neck mass		Preparation of slides for staining Hologic T2000 processor CYSOP170	HHH
		Staining Automated using stains as specified using in-house procedures in conjunction with manufacturer's instructions for Shandon Gemini AS PAP CYSOP164: Papanicolau: CYSOP024 May Grunwald Giemsa: CYSOP164	HHH
Wet preparations of respiratory and serous fluids	Identification of lipid	Manual staining using in-house procedures using stains: Diff quick: CYSOP208 Oil Red O: CYSOP236	HHH
Stained slides	Morphological assessment and interpretation/diagnosis	Microscopy (qualitative analysis) In-house procedures using light microscopy: CPSOP140	HHH

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