

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 9083 Accredited to ISO 15189:2012	Manchester University NHS Foundation Trust	
	Issue No: 004 Issue date: 08 September 2021	
	Department of Histopathology Wythenshawe Hospital Southmoor Road Wythenshawe Manchester M23 9LT	Contact: Ranjeev Kaur Deol Tel: +44 (0)161 291 4804 E-Mail: Ranjeev.Deol@MFT.NHS.UK Website: www.mft.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
Address Department of Histopathology Wythenshawe Hospital Southmoor Road Wythenshawe Manchester M23 9LT Local contact Ranjeev Kaur Deol Tel: +44 (0)161 291 4804 E-mail: Ranjeev.deol@mft.nhs.uk	Routine Histopathology Special Stains Immunohistochemistry DDISH Non-gynae Cytology Andrology service Mortuary Services (body receipt, storage and release, Record keeping (body identification and audit trail)	A
Microbiology Dept. Tameside General Hospital Fountain Street Ashton -under-Lyme OL6 9RW Local contact Dawn Clarke Tel: 0161 9226110 Email: Dawn.Clarke@tgh.nhs.uk	Andrology service	B



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
<p>HUMAN BODY TISSUE</p> <p>Tissues: biopsy, excision and resection and post mortem specimens</p> <p>Formalin Fixed Paraffin wax blocks of processed tissue.</p> <p>Tissue for frozen sections</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u></p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p>	<p>In house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified</p> <p>Specimen dissection downdraft benches: HI-S-CU-7 MO-S-23</p> <p>Tissue processing Shandon Excelsior tissue processors, HI-S-RO-1</p> <p>Tissue Embedding Using Leica and Thermo Shandon Embedding Centre HI-S-RO-7</p> <p>Tissue sectioning Using semi-automated Finesses Microtomes and automated Finesse Microtome's HI-S-RO-12 HI-S-RO-8</p> <p>Cryotomy Frozen sections Using Leica and Shandon cryostat. HI-S-CY43</p>	A



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological 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	A
FFPE slides and frozen sections	Routine morphological staining for the detection of: Basophilic and eosinophilic structures	Routine morphological staining using haematoxylin and Eosin (H&E) stain Sakura slide stainer HI-S-RO-13 Manual HI-S-SS-4	
FFPE slides	Special stains for the detection of: Acid Mucopolysaccharides Acid and neutral mucopolysaccharides Amyloid Elastic fibres and connective tissue Helicobacter/microorganisms Gram positive and negative microorganisms Fungi (Aspergillus and Pneumocystis) Elastic fibres and connective tissue Melanin, Argentaffin cells and lipofuscin pigment Connective tissue Connective tissue and fibrin Neutral mucopolysaccharides, glycogen and fungus Haemosiderin and ferric acid	Documented in-house procedures for manual (M) and automated (A) staining using the Ventana Benchmark for special stains: Acid Alcohol HI-S-SS-29 Alcian Blue HI-S-SS-6 (A) Alcian Blue Periodic Acid Schiff + / - Diastase HI-S-SS-7 (A) Congo Red HI-S-SS-8 (A) Elastic van Gieson HI-S-SS-10 (M) Giemsa HI-S-SS-10 (A) Gram stain HI-S-SS-12 (M) Grocott HI-S-SS-13 (A) HEEL HI-S-SS-10 (M) Masson Fontana HI-S-SS-17 (M) Masson Trichrome HI-S-SS-18 (A) Martius Scarlet Blue MSB for fibrin HI-S-SS-19 (M) Periodic Acid Schiff + / - Diastase HI-S-SS-20 (A) Perl's Prussian Blue HI-S-SS-21 (A)	



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological 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	A
FFPE slides (cont'd)	<p>Special stains for the detection of: (cont'd)</p> <p>Reticulin fibres</p> <p>Copper bound protein, Hep B virus</p> <p>Mast cells</p> <p>Connective tissue</p> <p>Tubercle bacilli</p> <p><u>Immunohistochemistry to detect the following:</u></p> <p>Muscle</p> <p>Smooth muscle</p> <p>ALK positive non-small cell lung carcinomas</p> <p>Embryonic cell in normal tissues and germ tumours</p> <p>Androgen Receptor</p> <p>Epithelium</p> <p>Diffuse lymph-proliferative disease and neoplastic cells of follicular lymphomas</p> <p>Follicular and germinal B cells</p> <p>T helper cells</p> <p>Smooth muscle cells</p> <p>Reacts with human calretinin and intracellular calcium binding protein. marker for mesotheliomas</p> <p>Epithelium</p> <p>Epithelium</p> <p>Dendritic cells</p>	<p>Documented in-house procedures for manual (M) and automated (A) staining using the Sakura slide stainer for special stains:</p> <p>Reticulin (Gordon and Sweets) HI-S-SS-5 (A)</p> <p>Shikata HI-S-SS-24 (M)</p> <p>Toluidine Blue HI-S-SS-25 (M)</p> <p>Van Gieson HI-S-SS-27 (M)</p> <p>Ziehl Neelsen HI-S-SS-1 (A)</p> <p>Automated with Roche Ventana Ultra: HI-S-IM-10</p> <p>Actin muscle specific Actin smooth muscle ALK-1</p> <p>Alpha feto protein</p> <p>Androgen Receptor B catenin BCL2 oncoprotein</p> <p>BCL6 C4D Caldesmon Calretinin</p> <p>Carcinoembryonic Antigen Carcinoembryonic Antigen 2 CD1a – dendritic cells</p>	



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HUMAN BODY TISSUE (cont'd) FFPE slides (cont'd)	<u>Immunohistochemistry to detect the following:</u> (cont'd) T cells Mature t cells, T cell lymphomas Granulocytes Reed-Sternberg cells Mature B cells, follicular dendritic cells B cells, some T cells B cells, Reed-Sternberg cells Reed-Sternberg cells and ALCL Haematopoietic cells, vascular endothelium T cells and some soft tissue Neuroendocrine cells Hodgkins and T cell marker Macrophages B lymphocytes Thyomas GIST Plasma cells Adenocarcinoma and carcinoid (intestinal epithelium) Tissues of neuroendocrine origin Expressed in variety of tumours Epithelial tissue from glandular to stratified squamous All epithelial types Squamous epithelium Non-squamous epithelium	In house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified Automated with Roche Ventana Ultra: HI-S-IM-10 CD3 – T cells CD5 CD10 CD15- leu m1 CD20 CD21 CD23 CD30 CD31 CD34 CD56 (NCAM) CD57 CD68 CD79A CD99 CD117 (CKIT) CD138 CDX2 Chromogranin A Cyclin D1 Cytokeratin MNF 116 Cytokeratin AE1/AE3 Cytokeratin 34βE12 Cytokeratin Cam5.2	A



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HUMAN BODY TISSUE (cont'd) FFPE slides (cont'd)	<u>Immunohistochemistry to detect the following:</u> (cont'd) Stratified squamous epithelium, basal cells, mesotheliomas Normal and neoplastic epithelia Epithelial cells Aid to detect papillary thyroid carcinoma Adenocarcinomas, columnar epithelial cells Viral inclusion bodies Gastrointestinal stromal tumours Mesothelioman and lymphatics Striated and smooth muscle cells Normal duct epithelial cells, ductal carcinoma Normal and neoplastic epithelium Epithelium – normal and neoplastic Dendritic cells Breast epithelium Erythrocytes Breast apocrine tumours Helicobacter pylori Hepatocytes Aid in assessment of breast cancer when Herceptin treatment is considered. Viral inclusion bodies	In house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified Automated with Roche Ventana Ultra: HI-S-IM-10 Cytokeratin CK5/6 Cytokeratin 7 Cytokeratin 14 Cytokeratin 19 Cytokeratin 20 Cytomegalo Virus Dog 1 D240 Desmin E-Cadherin Epithelial membrane antigen Epithelium (Ber EP4) Factor X111A GATA -3 Glycophorin A Gross Cystic disease fluid protein Helicobacter pylori Hep Par 1 HER-2 Herpes Simplex Virus 1	A



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HUMAN BODY TISSUE (cont'd) FFPE slides (cont'd)	<u>Immunohistochemistry to detect the following:</u> (cont'd) Light chains - Lambda Viral inclusion bodies Sex chord stromal tumours Proliferating cells B and T Cells Apocrine breast tumours Melanoma marker Melanoma marker Melanoma marker Neutrophils and monocytes Rhabdomyosarcoma Smooth muscle Nuclei of cells containing a high level of oestrogen HPV driven tumour Nuclei of cells containing a high level of oestrogen HPV driven tumour Squamous Epithelium Neoplastic cells in epithelium Molar Pregnancy Squamous epithelium Protein Levels of PD-L1 in tumour cells and immune cell infiltrates to predict response to anti-PD1 and PD-L1 directed therapies Prostate tumour detection Nuclei of cells showing expression of progesterone Pneumocystis carinii Prostate secretory and ductal epithelium	In house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified Automated with Roche Ventana Ultra: HI-S-IM-10 Immunoglobulin Kappa Immunoglobulin Lambda Inhibin Ki67 Leukocyte common antigen Mammaglobin Melan A Melanosome (HMB45) Myeloperoxidase Myogenin Myosin Napsin Oestrogen P16 P40 P53 P57 P63 P504S PAX-8 PD-L1 Placental alkaline phosphatase Progesterone Pneumocystis carinii Prostate Specific Antigen (PSA)	A



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HUMAN BODY TISSUE (cont'd)	<u>Immunohistochemistry to detect the following:</u> (cont'd) Prostate secretory and ductal epithelium Schwann cells. Nerve processes, S100 +ve neoplasms Neuroendocrine cells	In house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified Prostate Acid Phosphatase S100 Synaptophysin	A
FFPE slides (cont'd)	Lining blood vessels. Lymphatic vessels, mesothelial cells Thyroglobulin containing cells Thyroid and lung pneumocytes Thyroid and lung pneumocytes Endothelial cells Epithelial cells and smooth muscle in fallopian tube. Wilms tumour thyroid and lung pneumocytes	Automated with Roche Ventana Ultra: HI-S-IM-10 Thrombomodulin Thyroglobulin Thyroid Transcription Factor TTF1 SPT24 Vimentin VWF (Factor V111) WT1	
Breast tissue	Determination of Her2 gene status.	DDISH (chromogenic in-situ hybridization) HI-I-6, HI-S-IM-3 HI-S-IM-10 HI-S-IM-9	
FFPE slides (Formalin fixed paraffin embedded) tissue on glass slides	Morphological and cytological abnormalities	Interpretive/diagnostic microscopy HI_S-PR-5 HI-S-PR-4	



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>Fine needle aspirates – Breast, urine, sputum, endoscopy samples, joint fluids, thyroid, bronchoalveolar lavage and washings, cellular washings – peritoneal, bladder, kidney, cyst fluids, ascitic fluid, pleural fluid, and pericardial fluids,</p> <p>Prepared cytological samples on glass slides</p>	<p><u>Cytopathology (non-gynae) examination activities for the purpose of clinical diagnosis</u></p> <p>Examination of cellular material in order to identify or exclude morphological and cytological abnormalities</p> <p>Tinctorial stains for the demonstration of Cells (nuclei and cytoplasm) and micro organisms</p> <p>Morphological and cytological abnormalities</p>	<p>In house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified</p> <p>Diagnostic cytology (non-gynae) in house documented manual procedures for the preparation, screening and reporting.</p> <p>HI-S-CY25 GI-EUS-FNA HI-S-CY32 Preparation of Cytospins and Smears HI-S-CY33 Preparation of Cell Blocks</p> <p>HI-I-50 Quality assurance, checking of prepared slides and sending out to Pathologist for reporting HI-S-CY45 Preparation of bronchoalveolar lavages</p> <p>HI-S-CY20 Rapid Giemsa method for air dried smears</p> <p>Interpretive/diagnostic microscopy HI-S-PR-6</p>	<p>A</p>



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HUMAN BODY TISSUE (cont'd)	<u>Andrology examination activities for the purposes of clinical diagnosis</u>	Documented in house manual methods HI-S-CY13 & HI-S-CY14 for examination of direct wet preparation and centrifugated pellet based on WHO Manual 2010 (5 th Edition)	A & B
Semen ejaculate	Fertility Investigation semen analysis: - pH - Volume - Concentration - Count - Motility - Morphology	HI-S-CY13	
Semen (post vasectomy)	Post vasectomy semen analysis: -Absence/ presence of sperm - Motility	HI-S-CY14	
END			