


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

| | | |
|---|---|---|
|  <p>Accredited to ISO 15189:2012</p> | Royal Devon and Exeter Hospitals NHS Foundation Trust | |
| | Issue No: 001 Issue date: 16 August 2016 | |
| | Cellular Pathology Royal Devon & Exeter Hospital Church Lane Exeter Devon EX2 5AD United Kingdom | Contact: Ian Chandler Tel: +44 (0)1392 406402 Fax: +44 (0)1392 406402 E-Mail: Ian.Chandler@nhs.net.uk Website: www.rdehospital.nhs.uk |
| Testing performed at the above address only | | |

Locations covered by the organisation and their relevant activities

Laboratory locations:

| Location details | Activity |
|--|--|
| <p>Address Cellular Pathology Department Royal Devon & Exeter Hospital (Wonford) Church Lane Exeter Devon EX2 5AD United Kingdom</p> <p>Local contact Dr Ian Chandler Tel: +44 (0)1392 406402 Fax: +44 (0)1392 406402 Email: Ian.Chandler@nhs.net.uk</p> | Routine Histopathology Special Stains Immunohistochemistry Immunofluorescence Diagnostic Cytology (Non-Gynae) Cytology (Gynae) HPV Testing Mortuary Services Post-Vasectomy Semen Analysis |

Site activities performed away from the locations listed above:

| Location details | Activity |
|--|---|
| <p>Mortuary Royal Devon & Exeter Hospital (Wonford) Church Lane Exeter Devon EX2 5AD United Kingdom</p> | Mortuary Services (body receipt, storage and release) |
| <p>Histology Archives Royal Devon & Exeter Hospital (Heavitree) Gladstone Road Exeter Devon EX1 2ED United Kingdom</p> | Histology 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: biopsy, excision, resection and post-mortem specimens</p> <p>Formalin Fixed Paraffin wax blocks of processed tissue.</p> <p>Skin in Michel's Medium Renal tissue in saline Tissue for frozen sections</p> <p>FFPE slides (Formalin fixed paraffin embedded) tissue on glass slides</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 – HISOP058 Monmouth downdraft benches HISOP118 Cassette printers – HISOP034</p> <p>Tissue processing Manual procedures or using VIP or Excelsior Tissue processor (HISOP108, HISOP082, EXTDOC018, EXTDOC025, EXTDOC036)</p> <p>Decalcification using Faxitron SOP HISOP100 , HISOP002</p> <p>Tissue Embedding Using Leica and Sakura embedding stations (HISOP016, EXTDOC090, EXTDOC092)</p> <p>Tissue Sectioning Using Leica Microtomes, (HISOP030, HISOP028, EXTDOC028, EXTDOC031,)</p> <p>Cryotomy Intra-operative Frozen sections Using Shandon Cryostat (HISOP021, HISOP023, HISOP HISOP116, EXTDOC013)</p> <p>Interpretive/diagnostic microscopy (HISOP065, HISOP095)</p> |



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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 analysers in conjunction with manufacturers' instructions as specified: |
| FFPE slides (Formalin fixed paraffin embedded) and frozen sections | Routine morphological staining For the detection of: Basophilic and eosinophilic structures | Routine morphological staining Leica Autostainer using Haematoxylin and Eosin (H & E) stains – HISOP005, 006, 007, EXTDOC001, 002 & 032 Frozen Section Staining (Rapid H&E) HISOPSS029 |
| Frozen Sections | Special stains for the detection of: Lipids | Documented in-house procedures for manual special stains Fat Stains on Frozen Sections (Oil Red O) HISOPSS019 |
| FFPE slides | Acid Mucopolysaccharides Acid and Neutral Mucopolysaccharides Amyloid Elastic fibres and connective tissue Helicobacter/Microorganisms Gram positive and negative microorganisms Basophilic and eosinophilic structures Connective tissue and fibrin | Alcian Blue HISOPSS001 Alcian Blue/PAS HISOPSS002 Congo Red HISOPSS032 Elastic/Haematoxylin Van Gieson (EVG/HVG) HISOPSS017 & 012 Giemsa HISOPSS006 Gram HISOPSS009 Haematoxylin & Eosin (H&E) HISOPSS037 Martius Yellow, Brilliant Crystal Scarlet, Soluble Blue (MSB) |



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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 analysers in conjunction with manufacturers' instructions as specified: |
| FFPE slides | Special stains for the detection of: | Documented in-house procedures for manual special stains |
| | Melanin, Argentaffin cells and Lipofuscin pigment | Masson Fontana HISOPSS015 |
| | Connective tissue | Masson's Trichrome HISOPSS016 |
| | Neutral Mucopolysaccharides, glycogen and fungus | Periodic Acid Schiff (PAS) & Diastase PAS (D/PAS) HISOPSS021 |
| | Haemosiderin and ferric iron | Perl's Prussian Blue HISOPSS022 |
| | Muscle striations | Phosphotungstic Acid Haematoxylin (PTAH) HISOPSS023 |
| | Reticulin fibres | Reticulin HISOPSS008 |
| | Copper-associated protein and Hepatitis B-affected cells | Rhodanine HISOPSS024 |
| | Mast cells | Toluidine Blue HISOPSS026 |
| | Tubercle bacilli | Ziehl Nielsen (ZN) HISOPSS031 |
| | Bile | Fouchet HISOPSS033 |
| | Calcium | Von Kossa HISOPSS028 |
| | Copper assoc Protein and Hepatitis B | Orcein HISOPSS020 |
| | Fibrin | Martius Scarlet Blue HISOPSS014 |
| | Fungi (Aspergillus) and Pneumocystis | Grocott HISOPSS011 |



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| <p>HUMAN BODY TISSUE (cont'd)</p> <p>FFPE slides (cont'd)</p> <p>FFPE slides</p> | <p><u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Special stains for the detection of: (cont'd)</p> <p>Glycogen and Mucin</p> <p>Helicobacter Pylori</p> <p>Leprosy</p> <p>Plasma Cells e.g. BMT</p> <p>Carcinoid Tumour</p> <p>Spirochetes</p> <p>IDENTIFICATION OF: Antigens and antibodies in various auto-immune skin diseases</p> <p>Reacts with C3c fragment, native C3 and C3b</p> <p>Specific for alpha chains of human IgA</p> <p>Specific for gamma chains of human IgG</p> <p>Specific for mu chains of human IgM</p> | <p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Documented in-house procedures for manual special stains</p> <p>Southgates mucicarmine HISOPSS018</p> <p>Cresyl Fast Violet HISOPSS005</p> <p>Wade Fite HISOPSS029</p> <p>Giemsa HISOPSS006</p> <p>Grimelius HISOPSS010</p> <p>Warthin & Starry HISOPSS035</p> <p>Immunofluorescence technique Documented in-house procedures in conjunction with manufacturer's instructions for Fluorescent Microscope SOPS HISOP025, HISOP026, EXTDOC048, EXTDOC074</p> <p>C3c complement/FITC</p> <p>IgA/FITC</p> <p>IgG/FITC</p> <p>IgM/FITC</p> |



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| <p>HUMAN BODY TISSUE (cont'd)</p> <p>FFPE slides</p> | <p><u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Immunohistochemistry to detect the following:</p> <p>Macrophages, neutrophils, A1AT accumulation</p> <p>Embryonic cell in normal tissues and germ tumours</p> <p>HGPIN, prostate adenocarcinoma</p> <p>Amyloid</p> <p>Androgen Receptor eg breast tumours</p> <p>Alpha Smooth Muscle Actin</p> <p>Diffuse lymph-proliferative disease and neoplastic cells of follicular lymphomas.</p> <p>Epithelial cell types</p> <p>Range of B cell Lymphocytes</p> <p>T Helper Cells</p> <p>Ovarian cancer</p> | <p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>DAKO IHC OMNIS (HISOPIHC010, HISOPIHC011, HISOPIHC012 HISOPIHC013 HISOPIHC014) Dako Omnis Advanced User Guide EXTDOC097</p> <p>Incorporating the following antibodies (SOP.HIIHCVAL, HIIHCABREP):</p> <p>Alpha 1 Antitrypsin</p> <p>Alpha Fetoprotein</p> <p>AMACR (Racemase)</p> <p>Amyloid A – MC1</p> <p>AR411</p> <p>ASMA -1A4</p> <p>Bcl2 oncoprotein</p> <p>Ber Ep4</p> <p>BOB-1</p> <p>CD4</p> <p>CA 125</p> |



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| <p>HUMAN BODY TISSUE (cont'd)</p> <p>FFPE slides (cont'd)</p> | <p><u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Immunohistochemistry to detect the following: (cont'd)</p> <p>Parafollicular cells in thyroid and medullary thyroid carcinomas</p> <p>Reacts with human calretinin and intracellular calcium binding protein. Marker for mesotheliomas</p> <p>Smooth Muscle Cells</p> <p>Smooth Muscle Cells</p> <p>Glandular cells</p> <p>T cells</p> <p>T cells (helper+mature)</p> <p>Mature T cells, T cell lymphomas</p> <p>Mature B cells, follicular dentritic cells, CALLA</p> <p>Granulocytes Reed-Sternberg cells</p> <p>T Cell, NK cells</p> | <p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>DAKO IHC OMNIS (HISOPIHC010, HISOPIHC011, HISOPIHC012 HISOPIHC013 HISOPIHC014) Dako Omnis Advanced User Guide EXTDOC097</p> <p>Incorporating the following antibodies (SOP.HIIHCVAL, HIIHCABREP):</p> <p>Calcitonin</p> <p>Calretinin</p> <p>Caldesmon h-CD</p> <p>Calponin</p> <p>CAM 5.2</p> <p>CD3</p> <p>CD4</p> <p>CD5</p> <p>CD8</p> <p>CD10</p> <p>CD7</p> |



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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 analysers in conjunction with manufacturers' instructions as specified: |
| FFPE slides (cont'd) | Immunohistochemistry to detect the following: (cont'd) | DAKO IHC OMNIS (HISOPIHC010, HISOPIHC011, HISOPIHC012 HISOPIHC013 HISOPIHC014) Dako Omnis Advanced User Guide EXTDOC097 |
| | Reed-sternberg and lymphomas | CD15 |
| | Mature B cells, Follicular dendritic cells | CD20 |
| | B cells, some T cells | CD21 |
| | B Cells, Reed-Sternberg cells | CD23 |
| | Reed-Sternberg cells and ALCL | CD30 |
| | Haematopoietic cells, vascular endothelium | CD31 |
| | T cells and some soft tissue | CD34 |
| | Plasma cells and activated T-cells | CD38 |
| | Natural killer cells, neuroendocrine tissues | CD43 |
| | Reactive urothelium and Lymphocytes | CD44 |
| | Leukocyte common antigen | CD45 |
| | Neuroendocrine cells | CD56 |



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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 analysers in conjunction with manufacturers' instructions as specified: |
| FFPE slides (cont'd) | Immunohistochemistry to detect the following: (cont'd) | DAKO IHC OMNIS (HISOPIHC010, HISOPIHC011, HISOPIHC012 HISOPIHC013 HISOPIHC014) Dako Omnis Advanced User Guide EXTDOC097 |
| | Hodgkin's and T cell marker | CD57 |
| | Macrophages | CD68 |
| | B lymphocytes | CD79alpha |
| | GIST | CD117/CKIT |
| | Plasma cells | CD138 |
| | Adenocarcinoma and carcinoid (intestinal epithelium) | CDX2 |
| | Megakaryocytes | CD61 |
| | CEA glycoproteins in adenocarcinoma | CEA |
| | Tissues of neuroendocrine origin | Chromogranin |
| | CMV | CMV |
| | Expressed in variety tumours Eg Mantle cell lymphoma | Cyclin D1 |
| | Basal cells, filamentous keratins form glandular to stratified squamous, prostate adenocarcinoma | Cytokeratin (HMWCK/34βE12) |



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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 analysers in conjunction with manufacturers' instructions as specified: |
| FFPE slides (cont'd) | Immunohistochemistry to detect the following: (cont'd) | DAKO IHC OMNIS (HISOPIHC010, HISOPIHC011, HISOPIHC012 HISOPIHC013 HISOPIHC014) Dako Omnis Advanced User Guide EXTDOC097 |
| | Epithelial tissue from glandular to stratified squamous | Incorporating the following antibodies (SOP.HIIHCVAL, HIIHCABREP): Cytokeratin (MNF116) |
| | Stratified squamous epithelium, basal cells, mesotheliomas | Cytokeratin 5/6 |
| | Normal and neoplastic epithelia | Cytokeratin 7 |
| | Epithelial cells | Cytokeratin 14 |
| | Adenocarcinomas, columnar epithelial cells | Cytokeratin 20 |
| | Striated and smooth muscle cells | Desmin |
| | Normal duct epithelial cells, ductal carcinoma | E-Cadherin |
| | Normal and neoplastic epithelium | EMA |
| | V.W factor in endothelial cells | Factor VIII |
| | Mesothelial Cells | HBME1 |
| | Placental trophoblasts | HCG |



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| <p>HUMAN BODY TISSUE (cont'd)</p> <p>FFPE slides (cont'd)</p> | <p><u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Immunohistochemistry to detect the following: (cont'd)</p> <p>Melanoma, melanocyte differentiation</p> <p>Sex chord stromal tumours</p> <p>B cells and plasma cells</p> <p>Proliferating Cells</p> <p>B cells and plasma cells</p> <p>B cells, T cells, monocytes, macrophages</p> <p>Melanoma marker</p> <p>Neutrophil granulocytes, monocytes</p> <p>Granulocytes, monocytes and histiocytes</p> <p>Breast ductal carcinoma</p> <p>Rhabdomyosarcoma and Wilm's tumour</p> <p>Neural tissue</p> | <p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>DAKO IHC OMNIS (HISOPIHC010, HISOPIHC011, HISOPIHC012 HISOPIHC013 HISOPIHC014) Dako Omnis Advanced User Guide EXTDOC97</p> <p>Incorporating the following antibodies (SOP.HIIHCVAL, HIIHCABREP):</p> <p>HMB45</p> <p>Inhibin</p> <p>Kappa</p> <p>Ki 67</p> <p>Lambda</p> <p>LCA</p> <p>Melan-A</p> <p>Myeloperoxidase</p> <p>Lysozyme</p> <p>Mammaglobin</p> <p>Myogenin</p> <p>Neurofibrillary protein NFP</p> |



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| <p>HUMAN BODY TISSUE (cont'd)</p> <p>FFPE slides (cont'd)</p> | <p><u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Immunohistochemistry to detect the following: (cont'd)</p> <p>Alveolar macrophages, plasma cells, lung adenocarcinoma</p> <p>Peripheral nerves, neuroendocrine tumours</p> <p>Nuclei of cells containing a high level of oestrogen</p> <p>Neoplastic cells in epithelium</p> <p>Squamous epithelium</p> <p>HPV driven tumour eg Squamous cell carcinoma</p> <p>Glandular epithelium</p> <p>Neurones, melanocytes, neuroendocrine cells</p> <p>Germ cell tumours</p> <p>Pneumocystis jirovecii</p> <p>Nuclei of cells showing expression of Progesterone</p> | <p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>DAKO IHC OMNIS (HISOPIHC010, HISOPIHC011, HISOPIHC012 HISOPIHC013 HISOPIHC014) Dako Omnis Advanced User Guide EXTDOC097</p> <p>Incorporating the following antibodies (SOP.HIIHCVAL, HIIHCABREP):</p> <p>Napsin A</p> <p>NSE</p> <p>Oestrogen Receptors</p> <p>P53</p> <p>P63</p> <p>P16</p> <p>PAP</p> <p>PGP 9.5</p> <p>PLAP</p> <p>P. jirovecii</p> <p>Progesterone Receptors</p> |



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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 analysers in conjunction with manufacturers' instructions as specified: |
| FFPE slides (cont'd) | Immunohistochemistry to detect the following: (cont'd) | DAKO IHC OMNIS (HISOPIHC010, HISOPIHC011, HISOPIHC012 HISOPIHC013 HISOPIHC014) Dako Omnis Advanced User Guide EXTDOC097 |
| | Prostate secretory and ductal epithelium | Incorporating the following antibodies (SOP.HIIHCVAL, HIIHCABREP): PSA-P PSA-M PSMA |
| | Schwann cells, nerve processes, S100 +ve neoplasms eg Melanoma | S100 |
| | Smooth muscle cells, myoepithelial cells | Smooth Muscle Actin (SMA) |
| | Smooth muscle cells, myoepithelial cells | Smooth Muscle Myosin (SMM) |
| | Neuroendocrine cells | Synaptophysin |
| | Lining blood vessels, lymphatic vessels, mesothelial cells | Thrombomodulin |
| | Thyroglobulin containing cells | Thyroglobulin |
| | TTF-1 found in lung and thyroid (thyroid follicular cells) | TTF |
| | Cells of mesenchymal origin | Vimentin |
| | Epithelial cells and smooth muscle in fallopian tube. Wilms tumour | WT-1 |



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| <p>HUMAN BODY FLUIDS</p> <p>Fine needle aspirates – Breast, sputum, urine CSF, oesophageal washings and brushings, Conventional Bronchial Brushings, Serous fluids, Bronchial washings and Bronchial Alveolar lavage samples.</p> | <p><u>Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis</u></p> <p>Examination of cellular material in order to identify or exclude morphological and cytological abnormalities</p> <p>Demonstration of : Cells (nuclei and cytoplasm) and micro organisms</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 preparation Screening and Reporting CYNG02, CYNG03, CYNG04, CYNG05, CYNG06, CYNG07, CYNG08, CYNG09, CYNG10, CYNG11, CYNG11a, CYNG15, CYNG24, CYNG26, Cell Block Preparation CYNG20, Gelatin Foam Cell Block Preparation CYNG29 Preparation of LBC bronchial brushing specimens CYNGLBC01 Screening and reporting of non gynae cytology slides CYNG01</p> <p>Papanicolaou stain for Non-Gynae Specimens CYNG24 May-Grunwald & Giemsa stain for air dried slides CYNG08 Diff-Quick Staining Technique CYNG18 Papanicolaou staining on the Leica autostainer/ coverslipper CYLBC03</p> |
| <p>Liquid Based Cervical Cell Samples</p> | <p>Examination of cellular material in order to identify or exclude morphological and cytological abnormalities</p> | <p>Gynae-cytology preparation, Hologic T2000 Processor CYLBC01 Hologic T5000 autoloader Processor CYLBC10. Screening and reporting of cervical cytology slides CY05, CYG02, CYG04</p> |
| <p>Liquid Based Cervical Cell Samples</p> | <p>Molecular Techniques</p> <p>Detection of high-risk HPV DNA</p> | <p>Roche Cobas 4800 HR CYHPV1, CYHPV3.</p> |



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| <p>HUMAN BODY TISSUE</p> <p>Semen (Post Vasectomy)</p> | <p><u>Andrology examination activities for the purposes of clinical diagnosis</u></p> <p>Detection of spermatozoa</p> | <p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Documented in house manual method CYNG14, CYSA09, CY01, CYNG24, CYNG27 for examination of direct wet preparation and centrifuged pellet based on WHO Manual 2010 (5th Edition)</p> |
| END | | |