# Schedule of Accreditation

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**8038**

**Accredited to ISO 15189:2022**

## Cambridge University Hospitals NHS Foundation Trust

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**Histopathology CUHFT**
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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 | Location code |
|---|---|---|---|
| **Address**<br>Histopathology<br>Addenbrookes Hospital<br>1000 Discovery Drive<br>Trumpington<br>Cambridge<br>CB2 0AX | **Local contact**<br>Zahrah Rosun | Histopathology<br>Neuropathology<br>Non-gynae cytology<br>Microtomy<br>Immunohistochemistry<br>Electron microscopy | ADDHIS |
| **Address**<br>MOHS Clinic Addenbrookes's Out Patients Department<br>Addenbrookes Hospital<br>Hills Road<br>Cambridge<br>CB2 0QQ | **Local contact**<br>Zahrah Rosun | Frozen sections | MOHS |

**Site activities performed away from the locations listed above:**

| Location details | | Activity | Location code |
|---|---|---|---|
| **Address**<br>Histopathology<br>Store Room, Level 1,4<br>Addenbrookes Hospital<br>Hills Road<br>Cambridge<br>CB2 0QQ | **Local contact**<br>Zahrah Rosun | Storage of Specimens only | N/A |

DETAIL OF ACCREDITATION

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN BODY TISSUE | Histopathological examination activities for the purposes of clinical diagnosis | Documented in-house procedures | |
| | Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis | In House documented methods for staining and examination, all supported by SOPs and where relevant, manufacturer's instructions for the following methods where relevant): | ADDHIS |
| Fresh and Fixed tissue | | Specimen Dissection<br>Exakt Diamond Band Saw<br>Dakewe C100 laser cassette printer<br>Balance VWR Ohaus<br>ADD.HIS 2181<br>ADD.HIS 5604<br>ADD.HIS 5605 | ADDHIS |
| Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens | | Tissue Processing<br>Sakura VIP<br>ADD.HIS 5603 | ADDHIS |
| Formalin fixed calcified tissue | | Decalcification<br>Raymond Lamb incubator<br>ADD.HIS 5642 | ADDHIS |
| Formalin fixed tissue samples as above | | Embedding<br>Leica Histocore Embedding centre<br>ThermoFisher Scientific Paratrimmer<br>Thermo Histostar Embedding Centre<br>Leica EG1150 Embedding Centre<br>Heated Forceps<br>ADD.HIS 5572 | ADDHIS |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN BODY TISSUE (cont'd) | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | Documented in-house procedures | |
| Paraffin wax embedded tissue as above | | Microtomy<br>Leica RM2245 Rotary microtome<br>Leica Histocore Multicut microtome<br>Floatation baths<br>ADD.HIS 5633 | ADDHIS |
| Paraffin wax embedded tissue as above | | Automated microtomy<br>AS-410M automated sectioning device -Axlab.<br>ADD.HIS 5633 | ADDHIS |
| Paraffin wax embedded tissue as above | | Slide Etching<br>Leica IP S Inkjet Printer for microscope slides<br>ADD HIS 5941 | ADDHIS |
| Formalin fixed BMT tissue | | Decalcification<br>Menarini Bone stations<br>ADD.HIS 5722 | ADDHIS |
| | Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis | In House documented methods for staining and examination, all supported by SOPs and where relevant, manufacturer's instructions for cutting up, processing, embedding, sectioning, staining, microscopic assessment and pathologist reporting: | ADDHIS |
| Formalin fixed paraffin-embedded tissue (FFPE) | Routine Staining<br>For the demonstration of basophilic and eosinophilic structures | Haematoxylin and Eosin Staining<br>Automated and manual<br>Leica Spectra workstation<br>Thermo and Cellpath slide drying oven<br>ADD.HIS ADD.HIS 10868 | ADDHIS |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN BODY TISSUE (cont'd) | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | Documented in-house procedures | |
| Fresh tissue | Handling and preparation of fresh and frozen tissue for intra-operative diagnosis | Cryotomy<br>Specimen preparation and dissection<br>Leica CM1950UV Cryostat<br>Monmouth class 1micriobiology safety cabinet<br>ADD.HIS 32166 | ADDHIS |
| Frozen sections | Routine Staining of frozen sections for the demonstration of basophilic and eosinophilic structures | Haematoxylin and Eosin Staining<br>Automated staining on Thermo Lini-stainer<br>ADD.HIS.32166 | ADDHIS |
| | Lipid | Oil Red O<br>ADD.HIS 31724 | |
| FFPE | Special stains for the detection of: | Special Stains<br>Documented in-house manual procedures using stains as indicated: | ADDHIS |
| | Acid Mucins | Alcian Blue<br>ADD.HIS 31709 | |
| | Acid and neutral mucins | Alcian Blue Periodic Acid – Schiff with/ without Diastase<br>ADD.HIS 5962 | |
| | Acid Mucins | Alcian Blue with Hyaluronidase digestion<br>ADD.HIS 32340 | |
| | Calcium | Alizarin Red S<br>ADD.HIS 32179 | |
| | Esterase activity | Chloroacetate Esterase<br>ADD.HIS 31755 | |
| | Amyloid | Congo Red<br>ADD.HIS 31756 | |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN BODY TISSUE (cont'd) | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | Documented in-house procedures | |
| FFPE (cont'd) | Special stains for the detection of: (cont'd) | Special Stains<br>Documented in-house manual procedures using stains as indicated: | ADDHIS |
| | Elastin | Elastic Picro Sirius Red<br>ADD.HIS5924 | |
| | Bile pigments | Fouchet<br>ADD.HIS 31760 | |
| | Helicobacter Pylori | Giemsa<br>ADD.HIS 31712 | |
| | Haemopoetic cells | Giemsa<br>ADD.HIS 31761 | |
| | Bacteria | Gram<br>ADD.HIS 5875 | |
| | Bacteria | Gram Twort<br>ADD. HIS 5875 | |
| | Fungi | Grocott<br>ADD.HIS 31713 | |
| | Collagen | Haematoxylin Ponceau S and Haematoxylin van Gieson<br>ADD.HIS 5924 | |
| | Muscle striations Skeletal and cardiac) | Mallory's Phosphotungstic Acid-Haematoxylin<br>ADD.HIS 31773 | |
| | Fibrin, connective tissue | Martius Scarlet Blue<br>ADD.HIS 31722 | |
| | Melanin | Masson Hamperl<br>ADD.HIS 31715 | |
| | Connective tissue | Masson's Trichrome<br>ADD.HIS 31723 | |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN BODY TISSUE (cont'd) | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | Documented in-house procedures | |
| FFPE (cont'd) | Special stains for the detection of: (cont'd) | Special Stains<br>Documented in-house manual procedures using stains as indicated: | ADDHIS |
| | Elastin | Miller's Elastic Stain - Ponceau S<br>or van Gieson<br>ADD.HIS 5862 | |
| | Spirochetes | Modified Steiner<br>ADD.HIS 31730 | |
| | Acid Fast Bacilli (e.g atypical Mycobacterium tuberculosis) | Modified Ziehl Neelsen<br>ADD.HIS 5874 | |
| | Acid mucins | Mucicarmine<br>ADD.HIS 31733 | |
| | Glomerular basement membrane | Periodic Acid (Jones' Hexamine) Silver<br>ADD.HIS 31729 | |
| | Neutral mucins, polysaccharides including glycogen | Periodic Acid Schiff (PAS) using automated Gemini methods and Leica Spectra<br>ADD.HIS 5962<br>ADD.HIS 10868 | |
| | Acid and neutral mucins, polysaccharides including glycogen | Periodic acid-Schiff (PAS) with Diastase using automated Gemini methods<br>ADD.HIS 5962 | |
| | Ferric iron | Perls<br>ADD.HIS 31758 | |
| | Collagen | Picro-sirius red<br>ADD.HIS 5924 | |
| | Reticulin fibres | Reticulin<br>ADD.HIS 31716 | |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN BODY TISSUE (cont'd) | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | Documented in-house procedures | |
| FFPE (cont'd) | Special stains for the detection of: (cont'd) | Special Stains<br>Documented in-house manual procedures using stains as indicated: | ADDHIS |
| | Copper | Rhodanine<br>ADD.HIS 31728 | |
| | Elastin, copper associated protein and hepatitis B antigen infected cells | Shikata's Orcein<br>ADD.HIS 31719 | |
| | Amyloid | Sirius Red<br>ADD.HIS 32226 | |
| | Mast cells | Toluidine Blue<br>ADD.HIS 31732 | |
| | Elastin, copper associated protein and hepatitis B antigen infected cells | Victoria Blue<br>ADD.HIS 32329 | |
| | Calcium salts | Von Kossa<br>ADD.HIS 31734 | |
| | Acid Fast Bacilli e.g Mycobacterium tuberculosis) | Ziehl Neelsen<br>ADD.HIS 5874 | |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN BODY TISSUE (cont'd)<br><br>Paraffin wax tissue sections | <u>Immunohistochemistry to detect the following</u> | Documented in-house methods used in accordance with manufacturers (Leica's operating instructions for the use of Bond III automated immunostainers) and Roche operating instructions for the Benchmark Ultra<br>ADD.HIS.5678<br>ADD.HIS.32357<br>ADD.HIS 6061<br>ADD.HIS 6027<br>Incorporating the following antibodies: | ADDHIS |
| | Identification of hepatocytes in alpha-1 antitrypsin | Alpha-1-antitrypsin | |
| | Pituitary tumours | Adrenocorticotropin (ACTH) | |
| | Smooth muscle actin | Actin | |
| | Anaplastic large cell lymphomas ALCL) that are ALK positive | ALK-1 (CD246) | |
| | Anaplastic lymphomas kinase (ALK protein) non-small cell lung carcinoma (NSCLC) | ALK Lung (D5F3) | |
| | Amyloid | Amyloid A | |
| | Differential diagnosis of selected tumours of soft tissue, gastrointestinal tract, the pancreas, lung and female genital tract | β Catenin | |
| | Follicular lymphomas and various diffuse lymphoproliferative disease | BCL-2 (Oncoprotein) | |
| | Classification of B cell lymphomas | BCL-6 | |
| | Adenocarcinoma | Ber-EP4 (Epithelial Antigen) | |
| | Detection of BRAF V600E mutation | BRAF | |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN BODY TISSUE (cont'd) | Histopathology (cont'd) | Documented in-house procedures | |
| | Immunohistochemistry to detect the following (cont'd) | | ADDHIS |
| | Marker for antibody mediated acute renal allograft rejection | C4d | |
| | Clear cell Renal cell carcinoma | Carbonic Anhydrase IX | |
| | Detection of CA125 Ovarian cancer antigen) | CA125 | |
| | Calcitonin producing C cells, medullary thyroid carcinoma | Calcitonin | |
| | Myoepithelial cells, smooth muscle, leiomyosarcoma | Calponin (Basic) | |
| | Mesothelial cells, malignant mesothelioma | Calretinin | |
| | Dendritic cells, cortical thymocytes, langerhan cells and dermal dendrocytes | CD1a | |
| | Characterization of T cell disorders | CD2 | |
| | T cell marker in lymphoproliferative disorders | CD3 | |
| | Thymocytes and T-helper cells, Anaplastic large cell lymphomas, mycosis fungoides and unspecified peripheral T-cells lymphoma | CD4 | |
| | Diagnosis of lymphoma, T cells, subset of B cells in mantle zone | CD5 | |
| | Classification of tumours of T-cell origin | CD7 | |
| | T-cells, cytotoxic, suppressor | CD8 | |
| | Lymphomas | CD10 | |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN BODY TISSUE (cont'd) | Histopathology (cont'd) | Documented in-house procedures | |
| | Immunohistochemistry to detect the following (cont'd) | | ADDHIS |
| | Reed Sternberg cell, Hodgkin's lymphoma | CD15 | |
| | B cell marker, lymphoma | CD20 | |
| | Mature B cells, follicular dendritic cells, lymphoma | CD21 | |
| | Sub population of B cells, follicular dendritic cells, lymphoma | CD23 | |
| | Reed-Sternberg cells and identification of anaplastic large cell lymphoma | CD30 | |
| | Endothelial cells | CD31 | |
| | Endothelial marker | CD34 | |
| | Low grade B cell lymphomas and myeloid disease | CD43 | |
| | Leucocyte common antigen, lymphoma | CD45 | |
| | Neural cell adhesion molecule neuroendocrine cells | CD56 | |
| | Megakaryocytes and platelet marker | CD61 | |
| | Macrophages, monocytes, neutrophils, basophils, large lymphocytes | CD68K | |
| | Identification of macrophages, M4 myelomonocytic) and M5 monocytic) types of acute myeloid leukaemia and histiocytic sarcoma | CD68P | |
| | B cell marker | CD79a | |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN BODY TISSUE (cont'd) | Histopathology (cont'd) | Documented in-house procedures | |
| | Immunohistochemistry to detect the following (cont'd) | | ADDHIS |
| | MIC2 gene product | CD99 | |
| | Hematopoietic stem cells, melanocytes, mast cells, Cajal cells, germ cells, basal cells of skin and mammary duct epithelia. Identification of c-kit expressing tumours, differentiation between gastrointestinal stromal tumours and other intraabdominal mesenchymal tumours | CD117 (monoclonal) | |
| | Plasma cell marker, multiple myeloma | CD138 | |
| | Intestinal epithelial cells, colorectal carcinoma | CDX2 | |
| | Colorectal carcinoma and secretory meningiomas | Carcinoembrionic Antigen (CEA) | |
| | Neuroendocrine neoplasia | Chromagranin A | |
| | Squamous epithelia and basal cells, distinction between undifferentiated squamous cell carcinoma and adenocarcinoma, epithelioid mesothelioma and lung carcinoma and differential diagnosis of atypical proliferations of breast | CK5/6 | |
| | Glandular and transitional epithelial cells, identification of adenocarcinoma of the lung, breast, endometrium, thyroid, ovary, transitional cells urothelial) carcinoma and chromophobe renal cell carcinoma | CK7 | |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN BODY TISSUE (cont'd) | Histopathology (cont'd) | Documented in-house procedures | |
| | Immunohistochemistry to detect the following (cont'd) | | ADDHIS |
| | Glandular and transitional epithelial cells. Identification of adenocarcinoma and squamous cell carcinoma | CK8/18 | |
| | Squamous basal cell epithelia, myoepithelial of breast and parotid gland, mesothelium of umbilical cord and Hassall's corpuscles of thymus | CK14 | |
| | Squamous basal cell epithelia of larynx and prostate, myoepithelial cells of salivary gland, sebaceous glands and hair follicles, Squamous cell carcinoma, Hassalls corpuscles and epithelial cells of thymus | CK17 | |
| | Epithelial tumours and cholangiocellular carcinomas | CK19 | |
| | Urothelium, intestinal epithelium and Merkel cells | CK20 | |
| | Epithelial cell marker | CK AE1/3 | |
| | Epithelial cell marker | CK MNF | |
| | Cytomegalovirus infected cells | CMV | |
| | Cytomegalovirus infected cells- early gene RNA transcript | CMV ISH | |
| | Identification of mantle cell lymphomas | Cyclin D1 | |
| | Endothelium marker, identification of lymphatic invasion in a variety of cancers | D2-40 (podoplanin) | |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN BODY TISSUE (cont'd) | Histopathology (cont'd) | Documented in-house procedures | |
| | Immunohistochemistry to detect the following (cont'd) | | ADDHIS |
| | Smooth and striated muscle cells and mesothelial cells; identification of rhabdomyosacromas, leiomyomas and mesotheliomas | Desmin | |
| | Gastrointestinal stromal tumours | DOG-1 | |
| | Epithelial cell membranes, mammary duct epithelia and invasive breast carcinoma | E-CAD | |
| | Identification of latent EBV infection | EBER ISH | |
| | Epithelial cell marker | EMA | |
| | Semi- quantitative detection of human estrogen receptor fo of human breast carcinoma, management and, prognosis and prediction of outcome of breast cancer, detection of estrogen receptor in □- positive cells | EP1 | |
| | Bladder and breast cancers, determine response to hormone therapy and to refine the prognosis of breast cancer | GATA-3 | |
| | Astrocytes, ependymal cells, immature oligodendrocytes, immature chroid plexus cells | GFAP | |
| | GH secreting cells of pituitary | Growth hormone | |
| | Identification of erythroleukaemia, erythoid cells at almost all stages of differentiaition | Glycophorin A | |
| | Mesothelial cells, classification of mesotheliomas | HBME-1 | |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN BODY TISSUE (cont'd) | Histopathology (cont'd) | Documented in-house procedures | |
| | Immunohistochemistry to detect the following (cont'd) | | ADDHIS |
| | Demonstration of trophoblastic elements, germ cell tumours | HCG | |
| | Melanocytes, Classification of melanomas and melanocytic lesions; | HMB45 | |
| | H.Pylori infections in gastritis and gastric cancers | Helicobacter Pylori | |
| | Classification of splenic marginal zone lymphoma, mantle cell lymphoma, B-cell lymphocytic lymphoma and rare subsets of multiple myeloma | IgD | |
| | Evaluation of glomerular diseases, detection of plasma cells and related lymphoid cells containing IgG; classification of patients with B-cell neoplasia; distinguishing neoplastic monoclonal proliferation from reactive hyperplasia of plasma cells | IgG | |
| | Evaluation of glomerular diseases; diagnosis of IgG4-related disease | IgG4 | |
| | Evaluation of glomerular diseases, detection of plasma cells and related lymphoid cells containing IgM; classification of patients with B-cell neoplasia; distinguishing neoplastic monoclonal proliferation from reactive hyperplasia of plasma cells | IgM (Monoclonal) | |
| | Detection of Plasma cells and related lymphoid cells containing kappa light chains | Kappa | |
| | Detection of Plasma cells and related lymphoid cells containing kappa light chains | Lambada | |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN BODY TISSUE (cont'd) | Histopathology (cont'd) | Documented in-house procedures | |
| | Immunohistochemistry to detect the following (cont'd) | | ADDHIS |
| | Pituitary tumours | LH | |
| | Detection of Mast cells | MCT | |
| | Melanocytes; melanomas, adrenocortical carcinomas and angiomyolipomas | Melan-A | |
| | Demonstration of the Ki-67 antigen; classification of a variety of tumours | MIB1 | |
| | Diagnosis of melanoma and other melanogenic tumours; diagnosis of perivascular epithelioid cell tumours including angiomyolipoma | MITF | |
| | Classification of tumours of the intestinal tract; Identification of Lynch Syndrome | MLH1 | |
| | Differentiation between adenocarcinoma and reactive mesothelial cells | MOC31 | |
| | Classification of tumours of the intestinal tract; Identification of Lynch Syndrome | MSH2 | |
| | Classification of tumours of the intestinal tract; Identification of Lynch Syndrome | MSH6 | |
| | Subset of B cells in the light zone of the germinal centre plasma cells, activated T cells, haematolymphoid neoplasms; subclassification of lymphoid malignancies | MUM-1 | |
| | Detection of myeloperoxidase-positive cells, discrimination between lymphoid and myeloid disorders | Myeloperoxidase | |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN BODY TISSUE (cont'd) | Histopathology (cont'd) | Documented in-house procedures | |
| | Immunohistochemistry to detect the following (cont'd) | | ADDHIS |
| | Diagnosis of rhabdomyosarcomas and Wilm's tumors; detection of cells of skeletal muscle origin | Myogenin | |
| | Napsin A protei, identification of tumours of lung origin | Napsin A | |
| | Neurofilament protein; discrimination between Hirschsprung´s disease and allied enteric nervous system malformations | NFP | |
| | Neuroendocrine and neuronal cells.; peripheral nerves, neural and neuroendocrine tumours, such as neuroblastomas, retinoblastomas, desmoplastic malignant melanoma and small-cell lung cancer | NSE | |
| | P16 expression in cervical intraepithelial neoplasia and cervical squamous cell carcinoma; Identification of HPV infection | P16 | |
| | p53 expression in a variety of carcinomas | P53 | |
| | Assessment of p63 protein expression; basal cells in the epithelium of prostate; detection myoepithelial cells of the breast and parotid gland | P63 | |
| | Identification of malignancies of B cell origin | PAX5 | |
| | Qualitative detection of the programmed death ligand 1 (PD-L1) protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung cancer (NSCLC) | PD-L1 (SP263) | |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN BODY TISSUE (cont'd) | Histopathology (cont'd) | Documented in-house procedures | |
| | Immunohistochemistry to detect the following (cont'd) | | ADDHIS |
| | Neurons and neuroendocrine cells | PGP 9.5 | |
| | Seminomas and desmoplastic small round cell tumours; identification of germ cell tumours | PLAP | |
| | Intestinal tract tumours, Identification of Lynch Syndrome | PMS2 | |
| | Pituitary tumours | Prolactin | |
| | Progesterone receptor, breast, cervical and endometrial carcinomas; management, prognosis and prediction of outcome of breast cancer | Progesterone | |
| | Glandular epithelium of the prostate | PSA | |
| | Prostate glandular epithelium, prostatic carcinoma | PSAP | |
| | Identification of prostate adenocarcinoma | Racemase (AMACR) | |
| | Classification of S100-positive neoplasms malignant melanomas) | S100 | |
| | Myoepithelial cell | SMMHC | |
| | Melanoma cells and peripheral nerve sheath tumour cells | SOX-10 | |
| | Mantle cell lymphomas | SOX-11 | |
| | Polyoma virus infected cells | SV40 | |
| | Neuroendocrine tumours, neurons | Synaptophysin | |
| | Diagnosis of leukemias and lymphomas | TdT | |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN BODY TISSUE (cont'd) | Histopathology (cont'd) | Documented in-house procedures | |
| | Immunohistochemistry to detect the following (cont'd) | | ADDHIS |
| | Thyroid epithelial cells, well differentiated thyroid carcinomas | Thyroglobulin | |
| | Follicular epithelial cells of thyroid, Type II pneumocytes. lung and thyroid tumours | TTF-1 | |
| | TSH secreting cells of pituitary. Pituitary tumours | TSH | |
| | Mesenchymal cells | Vimentin | |
| | Wilms' tumour protein | WT-1 | |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN BODY TISSUE (cont'd) | Histopathology (cont'd)<br><br>Immunohistochemistry to detect the following (cont'd)<br><br>HER2 ICC | Documented in-house procedures | ADDHIS |
| Sections of paraffin wax embedded breast and GI tract tissue | Her2 postive cells in breast and gastric neoplastic tissue | Documented in-house method incorporating 4B5 antibodies used in accordance with manufacturers operating instructions for the Ventana Benchmark Ultra<br>ADD.HIS 6061ADD.HIS 6027 | ADDHIS |
| Slides prepared in house as above | Morphological assessment and interpretation/diagnosis<br><br>HER2 FISH | Qualitative Microscopy<br>Leica microscopy with screen<br>ADD.HIS 32357 | ADDHIS |
| Sections of paraffin wax embedded breast and GI tract tissue | Her2 postive cells in breast and gastric neoplastic tissue | Documented in house methods incorporating thermo-Brite and Abbott molecular Path vision DNA Probe kit II<br>ADD.HIS 6027 | ADDHIS |
| Slides prepared in house as above | Reading and interpretation of slides | Qualitative Microscopy<br>Various microscopes including Leitz, Olympus and Nikon<br>Voice recognition software<br>ADD.HIS 32375 | ADDHIS |
| Fresh Skin and tonsil biopsies | | Specimen receipt<br>VWR Rocking platform<br>ADD.HIS 32567 | ADDHIS |
| Frozen Skin and tonsil biopsies | Handling and preparation of frozen tissue for immunofluorescence | Cryotomy<br>Preparation and dissection for immunofluorescence<br>Cryostat Leica CM1950<br>ADD.HIS 32567 | ADDHIS |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN BODY TISSUE (cont'd) | Histopathology (cont'd) | | |
| Frozen sections | Immunohistochemistry to detect the following: | Documented in-house methods incorporating the following FITC labelled antibodies used in accordance with manufacturers operating instructions for the Ventana Benchmark Ultra<br>ADD.HIS 32567 | ADDHIS |
| | Gamma Chains | IgG fluorescein isothiocyanate | |
| | Alpha Chains | IgA fluorescein isothiocyanate | |
| | M chains | IgM fluorescein isothiocyanate | |
| | C3c fragment of complement, | C3 fluorescein isothiocyanate | |
| Slides prepared in house as above | Morphological assessment and interpretation/diagnosis | Qualitative Microscopy<br>Fluorescent Microscopy Olympus (Model BX63) for viewing immunofluorescence under UV light<br>ADD.HIS 31855 | ADDHIS |
| | Neuropathological examination activities for the purposes of clinical diagnosis of neuropathological diseases of the brain and nerve | Documented in-house procedures as indicated. | ADDHIS |
| Fresh, Fixed tissue | | Specimen Dissection<br>AFOS down flow table<br>Labcaire C1 special microbiology cabinet for fresh tissue<br>Dissection microscope GX stereo<br>Raymond Lamb Oven<br>ADD.HIS 32477<br>ADD.HIS 31876<br>ADD.HIS 31923<br>ADD.HIS 6303 | ADDHIS |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN BODY TISSUE (cont'd) | Histopathology (cont'd) | | |
| | Neuropathological examination activities for the purposes of clinical diagnosis of neuropathological diseases of the brain and nerve (cont'd) | Documented in-house procedures as indicated. | ADDHIS |
| Formalin fixed tissue | | Processing<br>Tissue Tek VIP processor<br>ADD.HIS 2152 | ADDHIS |
| Formalin fixed tissue | | Embedding<br>Leica Histocore<br>ThermoFisher Scientific Paratrimmer<br>Heated Forceps<br>ADD.HIS 32477 | ADDHIS |
| Formalin fixed wax embedded tissue samples | | Microtomy<br>Leica Histocore Multicut<br>Floatation baths<br>ADD.HIS 32477 | ADDHIS |
| Frozen tissue | Handling and preparation of brain and nerve tissue for frozen section | Cryotomy<br>Preparation and dissection of brain and nerve tissue<br>Leica CM3050SUV Cryostat<br>ADD.HIS. 10287ADD.HIS 31876 | ADDHIS |
| Paraffin wax sections | Routine Staining<br>For the demonstration of basophilic and eosinophilic structures | Haematoxylin and Eosin Staining<br>Automated Leica spectra workstation<br>ADD.HIS.10868 | ADDHIS |
| | Special stains for brain and nerve to detect the following: | Documented methods using stains as indicated | ADDHIS |
| Brain smears | General Metachromatic stain for cellular features | Preparation of Neuropath smear and Toluidine Blue<br>ADD.HIS 10287 | |
| Fresh, Fixed and Frozen tissue sections | Myelin | Luxol Fast Blue with Cresyl Fast Violet<br>ADD.HIS 31916 | |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN BODY TISSUE (cont'd) | Histopathology (cont'd) | | |
| Paraffin wax sections | Immunohistochemistry for brain to detect the following: | Documented in-house manual procedures using antibodies as indicated. ADD.HIS 31915 | ADDHIS |
| | Amyloid | BA4 | |
| | Amyloid | BAPP | |
| | Glial fibrillory | GFAP | |
| | Plaques and tangles | TAU (AT8) | |
| | Histopathological examination activities for the purposes of clinical diagnosis of muscle diseases: | Documented in-house procedures using stains as indicated. | ADDHIS |
| Fresh muscle tissue | Handling and preparation of muscle tissue for frozen section | Specimen Dissection and Preparation Cryostat Leica CM3050S ADD.HIS 31918 | ADDHIS |
| Frozen sections | Special stains for the detection of: | Documented methods using stains as indicated: | ADDHIS |
| | Lysosomes in muscle | Acid phosphatase ADD.HIS 31904 | |
| | Mitochondrial complexes | Cytochrome oxidase ADD.HIS 31908 | |
| | Mitochondrial complexes, Muscle structure | Gomori's Trichrome ADD.HIS 31911 | |
| | Nuclei and other cell components | Haematoxylin and Eosin ADD.HIS 31912 | |
| | Type 1 fibres | NADH Diaphorase ADD.HIS 31922 | |
| | Lipids | Oil red O ADD.HIS 31924 | |
| | Glycogen | Periodic acid Schiff ADD.HIS 31926 | |
| | SDH activity | Succinic Dehydrogenase ADD.HIS 31930 | |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN BODY TISSUE (cont'd) | Histopathology (cont'd) | | |
| Frozen sections | Immunohistochemistry for muscle to detect the following: | Documented in-house manual procedures using antibodies as indicated.<br>ADD.HIS 31915 | ADDHIS |
| | HLA class 1 complex<br>Muscle fibre type<br>Muscle fibre type | HLAABC<br>Myosin slow<br>Myosin fast | |
| | Diagnostic Electron Microscopy | | |
| | Examination of cellular material in order to identify or exclude morphological and cytological abnormalities | Documented in-house manual procedures using stains as indicated. | ADDHIS |
| Renal and nerve biopsies | | Tissue Processing<br>Astec monair plus fume cabinet<br>Sartorius balance<br>pH meter<br>TAAB oven<br>ADD.HIS 5605<br>ADD.HIS 31677 | ADDHIS |
| Formalin and glutaraldehyde fixed tissue samples | | Microtomy<br>Leica EMUC7 Ultra microtome<br>Leica KMR3 glass knive maker<br>Hot plate<br>ADD.HIS 2855 | ADDHIS |
| Formalin and glutaraldehyde fixed tissue samples | | Special Stain for EM | ADDHIS |
| Semi-thins | Organelles | Methylene Blue<br>ADD.HIS 31684 | |
| Ultra-thins | Organelles | Uranyl Acetate<br>ADD.HIS 31684 | |
| | Organelles | Lead Citrate<br>ADD.HIS 31684 | |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN BODY TISSUE (cont'd) | Histopathology (cont'd)<br><br>Morphological assessment and interpretation | Documented in-house procedures | |
| Formalin and Glutareldehyde Fixed Resin Embedded Tissue samples prepared as above | Demonstration of ultrastructural components of renal, muscle, nerve and other tissues.<br>Production of micrographs suitable for diagnostic use | Electron microscopy<br>Taking Diagnostic EM photographs, using documented in-house procedures in conjunction with manufacturer's instructions using Hitachi H7650<br>ADD.HIS 6367 | ADDHIS |
| HUMAN BODY FLUIDS | Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis | | ADDHIS |
| Body fluid Including:<br>Serous effusions<br>Cyst fluids<br>Urine including urinary tract washings)<br>Joint fluid<br>Fine needle aspiration, EUS or EBUS<br>Bronchial specimens including sputum, washings, brushings and lavages)<br>CSF<br>Eye fluid<br>GI tract brushings | Examination of cellular material in order to identify or exclude morphological and cytological abnormalities | In House documented methods for staining and examination, all supported by SOPs and where relevant, manufacturer's instructions for centrifuge and cytospin, and staining and coverslip. | ADDHIS |
| | | Specimen preparation<br>Sigma 316-P centrifuge<br>Shandon cytospin 3<br>ADD.HIS 32252<br>ADD.HIS 32269<br>ADD.HIS 31984<br>ADD.HIS 31968 | ADDHIS |
| | Routine Staining<br>For the demonstration of basophilic, eosinophilic and cynophilic structures for the differentiation of cell types and cytological abnormalities | Staining of cell preparations<br>Pap and Quick-Diff<br>Gemini autostainer<br><br>ADD.HIS 31977<br>ADD.HIS.31985 | ADDHIS |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN BODY FLUIDS (cont'd) | Cytopathology (Non-Gynae) (cont'd) | Documented in-house procedures | |
| Slides prepared in house as above | Morphological assessment and interpretation/diagnosis | Qualitative microscopy<br>Various microscopes including Nikon, Olympus, Leica<br>ADD.HIS 31981<br>ADD.HIS 32261<br>ADD.HIS 206 | ADDHIS |
| Joint fluids synovial fluids) | Assessment of birefringent crystals of monosodium urate and calcium pyrophosphate crystals | Microscopic examination:<br>Olympus BX45 microscope with polarising filters<br>ADD.HIS 31981 | ADDHIS |
| | Special Staining to identify or exclude morphological and cytological abnormalities: | Documented in-house procedures using stains as indicated: | ADDHIS |
| | Pneumocysti Carnii, fungi | Grocott<br>ADD.HID 31713 | |
| | Lipids | Oil red O<br>ADD.HIS 31724 | |
| | Iron | Perls<br>ADD.HIS 31758 | |
| Slides prepared in house as above for Non-gynae samples list above | Morphological assessment and interpretation/diagnosis | Qualitative Microscopy<br>ADD.HIS 32261<br>ADD.HIS 31981 | ADDHIS |
| | Histopathological examination activities for the purposes of clinical diagnosis of MOHS' | In House documented methods for staining and examination, all supported by SOPs and where relevant, manufacturer's instructions for sectioning and staining of frozen sections and pathologist reporting | MOHS |
| Frozen skin tissue | Examination of cellular material in order to identify or exclude morphological and cytological abnormalities | Cryotomy/frozen sections<br>Leica cryostat<br>ADD.HIS 5702 | MOHS |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---|
| HUMAN BODY FLUIDS (cont'd) | Cytopathology (Non-Gynae) (cont'd) | Documented in-house procedures | |
| | Histopathological examination activities for the purposes of clinical diagnosis of MOHS' (cont'd) | In House documented methods for staining and examination, all supported by SOPs and where relevant, manufacturer's instructions for sectioning and staining of frozen sections and pathologist reporting | MOHS |
| Frozen skin tissue | Routine Staining<br>For the demonstration of basophilic and eosinophilic structures | Routine Haematoxylin and Eosin staining<br>Linistainer<br>ADD.HIS 5702 | MOHS |
| Slides prepared in house as above | Morphological assessment and interpretation/diagnosis | Qualitative Microscopy<br>Olympus Microscope<br>ADD.HIS 5702 | ADDHIS |
| END | | | |