


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

| | | |
|--|--|--|
|  UKAS MEDICAL 9560 Accredited to ISO 15189:2012 | Warrington and Halton Teaching Hospitals NHS Foundation Trust | |
| | Issue No: 005 Issue date: 09 February 2020 | |
| | Histopathology Department Warrington Hospital Lovely Lane Warrington WA5 1QG United Kingdom | Contact: Steve Acton Tel: +44 (0)1925 275592 E-Mail: s.acton1@nhs.net Website: www.whh.nhs.uk/ServiceCatInfo.asp?id=31 |
| 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 Histopathology Department Warrington Hospital Lovely Lane Warrington WA5 1QG Local contact Carol Taylor Tel: 01925 665092 | Histology Non-Gynae Cytology FNA clinic (Head and Neck: Breast Screening Suite) Mortuary: Storage and release of bodies Hospital and Coronial Post mortems Retrieval of tissue from Post mortem | A |

Site activities performed away from the locations listed above:

| Location details | Activity | Location code |
|---|---|---------------|
| Address Halton Hospital Hospital way Runcorn WA7 2DA Local contact Carol Taylor Tel: 01925 665092 | Mortuary: Storage and release of bodies | B |



9560
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Warrington and Halton Teaching Hospitals NHS Foundation Trust
Issue No: 005 Issue date: 09 February 2020

Testing performed by the Organisation at the locations specified

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 AND FLUIDS</p> <p>Tissue samples: Formalin fixed paraffin embedded (FFPE), fresh and frozen.</p> | <p><u>Histopathological examination activities for the purposes of clinical diagnosis</u></p> <p>The examination of tissues to exclude or identify morphological and cytological abnormalities for the purpose of clinical diagnosis</p> | <p>In-house documented procedures using manual methods or analysers as specific in conjunction with manufacturers' instructions as specified:</p> <p>Macroscopic and Microscopic examination supported by:</p> <p>Histology cut-up Using manual methods. SOP: HC-CU-1</p> <p>Dissection of small specimens using manual methods. SOP: HC-CU-1, HC-PA-2, HC-PA-3, HC-PA-12, HC-PA-15, HC-PA-22, HC-PA-23, HC-PA-24, HC-PA-31, HA-PA-32, HC-PA-36, HC-PA-40, HC-PA-42, HC-PA-44, HC-PA-49, HC-PA-51, HC-PA-55, HC-PA-56, HC-PA-57, HC-PA-59, HC-PA-60</p> <p>Dissection of large spec using manual methods. SOP: HC-CU-1, HC-PA-2, HC-PA-7, HC-PA-8, HC-PA-9, HC-PA-11, HC-PA-13, HC-PA-14, HC-PA-16, HC-PA-17, HC-PA-18, HC-PA-19, HC-PA-20, HC-PA-21, HC-PA-26, HC-PA-28, HC-PA-29, HC-PA-30, HC-PA-31, HC-PA-32, HC-PA-33, HC-PA-34, HC-PA-35, HC-PA-37, HC-PA-39, HC-PA-39, HC-PA-41, HC-PA-43, HC-PA-45, HC-PA-46, HC-PA-47, HC-PA-52, HC-PA-53, HC-PA-54, HC-PA-62, HC-PA-63, HC-PA-64.</p> <p>Tissue Processing using Thermofisher Excelsior and Excelsior ES. SOP: HC-CU-14</p> | <p>A</p> |



9560
Accredited to
ISO 15189:2012

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

Warrington and Halton Teaching Hospitals NHS Foundation Trust

Issue No: 005 Issue date: 09 February 2020

Testing performed by the Organisation at the locations specified

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|--|--|---|---------------|
| HUMAN BODY TISSUE AND FLUIDS (cont'd) | <u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u> | In-house documented procedures using manual methods or analysers as specific in conjunction with manufacturers' instructions as specified: | |
| Tissue samples: fresh and frozen. | The examination of tissues to exclude or identify morphological and cytological abnormalities for the purpose of clinical diagnosis | Cryomicrotomy and Intraoperative Frozen Sections using manual staining methods and the Leica CM1900 cryostat. SOP: HC-CU-20 | A |
| Tissue samples: Formalin fixed paraffin embedded (FFPE). | The examination of tissues to exclude or identify morphological and cytological abnormalities for the purpose of clinical diagnosis (cont'd) | Macroscopic and Microscopic examination supported by: (cont'd) Embedding using Thermofisher Histostars. SOP: HC-BS-12 Section Cutting using Leica RN 2125 and 2145 microtomes. SOP: HC-BS-12 Automated H&E staining by Leica autostainer and cover-slipper using SOP HC-BS-7 | A |
| Stained FFPE slides/ Cytology prepared slides | Morphological assessment/interpretation and diagnosis of Histological and Cytological specimens | Microscopy using a range of consultant grade microscopes with Medical Reporting via MOLIS AP LIMS software using SOP HC-CO-45 | A |
| Formalin-fixed paraffin embedded tissue slides | Demonstration of: Basophilic and eosinophilic structures Acid mucins | Special Tinctorial Histochemical Staining Methods SOP Manual techniques Routine H&E staining using a manual method SOP: HC-SS-11 Alcian Blue Technique using a manual method. SOP: HC-SS-4 | A |



9560
Accredited to
ISO 15189:2012

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

Warrington and Halton Teaching Hospitals NHS Foundation Trust

Issue No: 005 Issue date: 09 February 2020

Testing performed by the Organisation at the locations specified

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|--|---------------|
| HUMAN BODY TISSUE AND FLUIDS (cont'd) | <u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u> | In-house documented procedures using manual methods or analysers as specific in conjunction with manufacturers' instructions as specified: | A |
| Formalin-fixed paraffin embedded tissue slides (cont'd) | Demonstration of: (cont'd) | Special Tinctorial Histochemical Staining Methods SOP Manual techniques (cont'd) | |
| | Acid and Neutral mucins | Alcian Blue – Periodic Acid-Schiff ± Diastase using a manual method. SOP HC-SS-5 | |
| | Amyloid – Secondary | Congo Red (Highman) using a manual method. SOP: HC-SS-6 | |
| | Bacteria | Gram Stain using a manual method. SOP: HC-SS-9 | |
| | Helicobacter | Giemsa Stain using a manual method. SOP: HC-SS-8 | |
| | Connective tissue | Van Gieson using a manual method. SOP: HC-SS-22 | |
| | Fungi or Pneumocystis | Grocott Methenamine using a manual method. SOP: HC-SS-10 | |
| | Glycogen and mucins | PAS ± Diastase using a manual method. SOP: HC-SS-17 | |
| | Haemosiderin | Perl's Prussian Blue Stain using a manual method. SOP: HC-SS-18 | |
| | Inclusion bodies/ reticulin | Orcein (Shikata) Stain using a manual method. SOP: HC-SS-20 | |
| | Mast cells | Toluidine Blue using a manual method. SOP: HC-SS-21 | |
| | Melanin | Masson Fontana using a manual method. SOP: HC-SS-13 | |



9560
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Warrington and Halton Teaching Hospitals NHS Foundation Trust
Issue No: 005 Issue date: 09 February 2020

Testing performed by the Organisation at the locations specified

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|--|--|---------------|
| HUMAN BODY TISSUE AND FLUIDS (cont'd) | <u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u> | In-house documented procedures using manual methods or analysers as specific in conjunction with manufacturers' instructions as specified: | |
| Formalin-fixed paraffin embedded tissue slides (cont'd) | Demonstration of: (cont'd) | Special Tinctorial Histochemical Staining Methods SOP Manual techniques (cont'd) | A |
| | M Tuberculosis | Ziehl Neelsen (ZN) using a manual method. SOP: HC-SS-24 | |
| | Reticulin Fibres | Gordon and Sweet Stain using a manual method. SOP: HC-SS-19 | |
| | Elastin | Miller's Elastic Van Gieson using a manual method. SOP: HC-SS-16 | |
| Formalin-fixed paraffin embedded tissue slides | Immunohistochemistry for the detection of: | Automated Immunohistochemistry In conjunction with manufacturer's instructions for Roche Ultra SOP: HC-IMM-17 and HC-IMM-18; incorporating the following antibodies: - | A |
| | Squamous epithelium, follicular epithelia in thyroid, epithelia and mesothelium in small and large bowel | 34Be12 (HMWCK) | |
| | Smooth Muscle, soft tissue tumour such as leiomyosarcomas | Actin (SMA) | |
| | Follicular and diffused large cell lymphomas from reactive lymph nodes | BCL-2 | |



9560
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Warrington and Halton Teaching Hospitals NHS Foundation Trust
Issue No: 005 Issue date: 09 February 2020

Testing performed by the Organisation at the locations specified

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|--|--|---------------|
| <p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Formalin-fixed paraffin embedded tissue slides (cont'd)</p> | <p><u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Immunohistochemistry for the detection of: (cont'd)</p> <p>Diffuse large B cell lymphomas and Burkitt's lymphoma and Reed Sternberg cells in Hodgkin's disease</p> <p>Epithelial Cells of the Colon.</p> <p>B cells, plasma cells</p> <p>Luminal cells of fallopian tubes, Ovarian epithelial malignancies</p> <p>Classification of mesothelial cells and malignant mesothelioma of the epithelial type</p> <p>Adenocarcinoma of intestinal origin</p> <p>Normal and neoplastic T cells from thymocytes to mature T cells</p> <p>Inducer T cells both normal and neoplastic</p> <p>T cell lymphomas and mantle cell lymphoma</p> | <p>In-house documented procedures using manual methods or analysers as specific in conjunction with manufacturers' instructions as specified:</p> <p>Automated Immunohistochemistry In conjunction with manufacturer's instructions for Roche Ultra SOP: HC-IMM-17 and HC-IMM-18; incorporating the following antibodies: - (cont'd)</p> <p>BCL-6</p> <p>BerEP4</p> <p>BOB-1</p> <p>CA125</p> <p>Calretinin</p> <p>CDX2</p> <p>CD3</p> <p>CD4</p> <p>CD5</p> | <p>A</p> |



9560
Accredited to
ISO 15189:2012

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

Warrington and Halton Teaching Hospitals NHS Foundation Trust

Issue No: 005 Issue date: 09 February 2020

Testing performed by the Organisation at the locations specified

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---------------|
| HUMAN BODY TISSUE AND FLUIDS (cont'd) | <u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u> | In-house documented procedures using manual methods or analysers as specific in conjunction with manufacturers' instructions as specified: | A |
| Formalin-fixed paraffin embedded tissue slides (cont'd) | Immunohistochemistry for the detection of: (cont'd) | Automated Immunohistochemistry In conjunction with manufacturer's instructions for Roche Ultra SOP: HC-IMM-17 and HC-IMM-18; incorporating the following antibodies: - (cont'd) | |
| | T cells cytotoxic / suppressor | CD8 | |
| | All germinal centre cells – tonsil Renal cell carcinoma | CD10 | |
| | Granulocytes, Reed-Sternberg cells. | CD15 | |
| | B cells | CD20 | |
| | Follicular dendritic cells | CD21 | |
| | Small B cell lymphocytic lymphoma. | CD23 | |
| | Reed Sternberg cells in Hodgkin's lymphoma, anaplastic large cell lymphoma and plasma cells | CD30 | |
| | Endothelial cells. Benign and malignant vascular disorders | CD31 | |
| | Leucocyte differentiation | CD34 | |
| | All Leucocytes | CD45 (LCA) | |
| | Neural / neuroendocrine tissue and natural killer cells | CD56 | |



9560
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Warrington and Halton Teaching Hospitals NHS Foundation Trust
Issue No: 005 Issue date: 09 February 2020

Testing performed by the Organisation at the locations specified

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---------------|
| HUMAN BODY TISSUE AND FLUIDS (cont'd) | <u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u> | In-house documented procedures using manual methods or analysers as specific in conjunction with manufacturers' instructions as specified: | A |
| Formalin-fixed paraffin embedded tissue slides (cont'd) | Immunohistochemistry for the detection of: (cont'd) | Automated Immunohistochemistry In conjunction with manufacturer's instructions for Roche Ultra SOP: HC-IMM-17 and HC-IMM-18; incorporating the following antibodies: - (cont'd) | |
| | Macrophages | CD68 | |
| | B cells all stages | CD79a | |
| | KIT protein in gastro-intestinal stromal tumours | CD117 | |
| | Plasma cells | CD138 | |
| | Adenocarcinoma | CEA | |
| | Neuroendocrine cells | Chromogranin A | |
| | Glandular and stratified squamous epithelium | CK (AE/AE3) | |
| | Myoepithelial cells of the prostate / breast. Squamous cell carcinoma | CK5/6 | |
| | Adenocarcinomas of breast, lung, endometrium, ovary, thyroid and carcinomas of bladder and renal cell | CK7 | |
| | Epithelial cells | CK8/18 | |
| | Basal cell marker | CK14 | |



9560
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Warrington and Halton Teaching Hospitals NHS Foundation Trust
Issue No: 005 Issue date: 09 February 2020

Testing performed by the Organisation at the locations specified

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---------------|
| HUMAN BODY TISSUE AND FLUIDS (cont'd) | <u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u> | In-house documented procedures using manual methods or analysers as specific in conjunction with manufacturers' instructions as specified: | A |
| Formalin-fixed paraffin embedded tissue slides (cont'd) | Immunohistochemistry for the detection of: (cont'd) | Automated Immunohistochemistry In conjunction with manufacturer's instructions for Roche Ultra SOP: HC-IMM-17 and HC-IMM-18; incorporating the following antibodies: - (cont'd) | |
| | Columnar cell epithelium | CK20 | |
| | Smooth and striated muscle tumours | Desmin | |
| | Adenocarcinoma from mesothelioma and ductal vs lobular cancer of the breast | E-Cadherin | |
| | Variety of normal and neoplastic epithelia | EMA | |
| | Oestrogen receptors breast carcinoma | ER | |
| | CerbNeu protein | HER2 | |
| | Melanoma cells | HMB-45 | |
| | Melanoma | Melan A | |
| | Proliferating cells in germinal B cells | MIB-1 (Ki67) | |
| | B cells | OCT 2 | |



9560
Accredited to
ISO 15189:2012

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

Warrington and Halton Teaching Hospitals NHS Foundation Trust

Issue No: 005 Issue date: 09 February 2020

Testing performed by the Organisation at the locations specified

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|---|---------------|
| HUMAN BODY TISSUE AND FLUIDS (cont'd) | <u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u> | In-house documented procedures using manual methods or analysers as specific in conjunction with manufacturers' instructions as specified: | A |
| Formalin-fixed paraffin embedded tissue slides (cont'd) | Immunohistochemistry for the detection of: (cont'd) | Automated Immunohistochemistry In conjunction with manufacturer's instructions for Roche Ultra SOP: HC-IMM-17 and HC-IMM-18; incorporating the following antibodies: - (cont'd) | |
| | Placental trophoblasts | PLAP | |
| | Breast carcinoma | Progesterone | |
| | Prostate secretory and ductal epithelium | PSA | |
| | Malignant change in cervical epithelium, HPV | P16 | |
| | Prostate basal cells, glandular epithelium | P63 | |
| | Schwann cells, adipocytes, cartilage | S100 | |
| | Islets of Langerhans cells | Synaptophysin | |
| | Lymphomas in lung and thyroid. | TTF-1 | |
| | Cells of mesenchymal origin | Vimentin | |



9560
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Warrington and Halton Teaching Hospitals NHS Foundation Trust
Issue No: 005 Issue date: 09 February 2020

Testing performed by the Organisation at the locations specified

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|--|--|--|---------------|
| HUMAN BODY TISSUE AND FLUIDS (cont'd) | <u>Cytopathological (Non-Gynae) examination activities for the purposes of clinical diagnosis</u> | In-house documented procedures using manual methods or analysers as specific in conjunction with manufacturers' instructions as specified: | |
| Body fluids/Fine Needle Aspirations Hydrocele and renal Cyst, Cerebro-spinal fluid (CSF), Sputum, Bronchio-alveolar lavage Bronchial washings, EBUS specimens, urine | The examination of body fluid/fine needle aspirate samples to exclude or identify morphological and cytological abnormalities for the purpose of clinical diagnosis Demonstration of: | Documented in-house procedures SOP: Non Gynae Cytology In conjunction with manufacturer's instructions for Shandon Cytopsins, Thermo Labofuge 400, EPC, Leica 5010 Autostainer, Leica 5030 coverslipper. | A |
| | Macroscopic and Microscopic analysis of cells (nuclei and cytoplasm) and micro organisms | Tinctorial stains Papanicolaou stain using the Thermo Varistain. SOP: HC-NG-1, HC-NG-9, HC-NG-21, HC-NG-23, HC-NG-27. | A |
| | Preparation of cell blocks for histology processing and staining | Non Gynae Cytology using manual methods and the Thermo Excelsior processors. SOP: HC-NG-16 | A |
| Fine Needle Aspirations (Head & Neck) | The examination of fine needle aspirate samples to exclude or identify morphological and cytological abnormalities for the purpose of clinical diagnosis | Diagnostic cytology (non-gynae) using manual methods and manual staining via rapid Romanowsky stain (Hemacolor) and mitotic microscope using SOP: HC-NG-23. | A |
| END | | | |