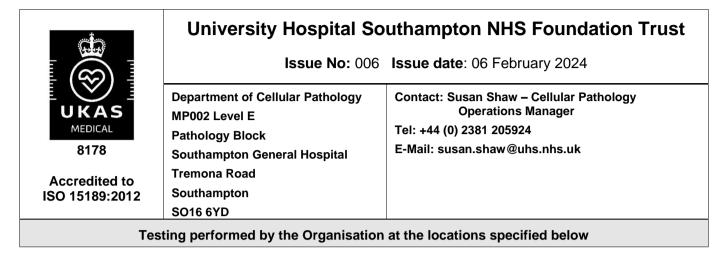
# **Schedule of Accreditation**

issued by

**United Kingdom Accreditation Service** 

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



#### Locations covered by the organisation and their relevant activities

#### Laboratory locations:

| Location details  |  | Activity  | Location code |
|---|--|---|---------------|
| Address<br>Department of Cellular Pathology<br>Levels E & B<br>Pathology Block<br>Southampton General Hospital<br>Tremona Road<br>Southampton<br>SO16 6YD | Local Contact<br>Susan Shaw<br>Cellular Pathology Operations<br>Manager<br>Tel : +44 (0) 2381 205924<br>Email :susan.shaw@uhs.nhs.uk | Histopathology<br>Neuropathology<br>Immunocytochemistry<br>Non-Gynae Cytopathology<br>Electron Microscopy | A             |

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

| Location details  |   | Activity  | Location code |
|---|---|---|---------------|
| EUS & EBUS Clinics<br>Endoscopy Department<br>Level E<br>Southampton General Hospital<br>SO16 6YD | Local Contact<br>Sharon Kooner-Evans<br>Tel: +44 (0) 2381204879<br>Sharon.kooner-<br>evans@uhs.nhs.uk | Assessment of adequacy of cellular material for diagnostic purposes.  | В             |
| FNA Clinic<br>Southampton General Hospital  | Local Contact<br>Sharon Kooner-Evans<br>Tel: +44 (0) 2381204879<br>Sharon.kooner-<br>evans@uhs.nhs.uk | Assessment of adequacy of cellular material for diagnostic purposes.  | С             |
| MOHS<br>Room CC162<br>Level C<br>Max-fax outpatient clinic<br>Southampton General hospital        | Local Contact<br>Sharon Kooner-Evans<br>Tel: +44 (0) 2381204879<br>Sharon.kooner-<br>evans@uhs.nhs.uk | micrographic surgery clinic<br>service - Frozen section<br>analysis of human tissue<br>samples to aid in clinical<br>assessment and diagnosis | D             |



ISO 15189:2012

## Schedule of Accreditation issued by

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

#### University Hospitals Southampton NHS Foundation Trust

Issue No: 006 Issue date: 06 February 2024

Testing performed by the Organisation at the locations specified

#### DETAIL OF ACCREDITATION

| Materials/Products<br>tested  | Type of test/Properties measured/Range<br>of measurement                                     | Standard specifications/<br>Equipment/Techniques used   | Location<br>Code |
|---|--|---|------------------|
| HUMAN BODY<br>FLUIDS AND<br>TISSUES                                   | Histopathology   |   |                  |
|   | Preparation and examination to identify or exclude morphological & cytological abnormalities | Macroscopic and Microscopic<br>examination using in-house<br>procedures (listed) in<br>conjunction with<br>manufacturer's instructions for<br>the following methods (where<br>relevant) |                  |
| Fresh frozen human<br>tissue samples for<br>Neuropathology only       | Frozen section identification of:  | <u>Cryotomy</u><br>Bright CryostatLP 120 006  | A                |
| Fresh frozen human<br>tissue samples                                  |  | Leica CM1950 Cryostat<br>Hand staining<br>LP 103 002  | A                |
|   |  | Immunofluorescence  |                  |
| Fresh frozen<br>human skin,<br>mucosal and<br>conjunctival<br>samples | Identification and detection of IgG, IgA and C3 antigens.                                    | Sectioned using Leica cryostat<br>CM1950.<br>Stained on the Ventana<br>BenchMark Ultra automated<br>IHC staining platform;  | A                |
|   |  | Documented in-house<br>procedures LP 130 007 & LP<br>130 022 in conjunction with<br>manufacturers instructions<br>using Ventana BenchMark<br>Ultra.                                     |                  |
|   |  | LP103 009 Treatment of<br>Specimens Requiring<br>Immunofluorescence Studies   |                  |
| Formalin fixed tissue samples   |  | Specimen dissection<br>Manual methods<br>LP 500 302   | A                |
|   |  |   |                  |

|                                 | Schedule of Accreditation<br>issued by<br>United Kingdom Accreditation Service<br>2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR UK |
|---------------------------------|---|
| UKAS                            | University Upenitele Southematen NUS Foundation Truct   |
| 8178                            | University Hospitals Southampton NHS Foundation Trust   |
| Accredited to<br>ISO 15189:2012 | Issue No: 006 Issue date: 06 February 2024  |
|                                 | Testing performed by the Organisation at the locations specified  |

| Materials/Products<br>tested        | Type of test/Properties measured/Range<br>of measurement | Standard specifications/<br>Equipment/Techniques used  | Location<br>Code |
|-------------------------------------|--|--|------------------|
| HUMAN BODY<br>FLUIDS AND<br>TISSUES | <u>Histopathology</u>                                    |  |                  |
|                                     |  | Tissue Processing  |                  |
| Formalin fixed tissue samples       |  | Peloris II tissue processor<br>Peloris III tissue processor<br>LP 104 002, LP 104 004, LP<br>104 009, LP 104 011, LP 120<br>013 & LP 120 050 | A                |
| Fresh and formalin fixed tissue     |  | Sakura VIP-6 for<br>neuropathology only<br>LP 104 002, LP 104 004, LP<br>104 009, LP 104 011, LP 120<br>013 & LP 120 050                     | A                |
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United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR UK

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|---|---|--|------------------|
| HUMAN BODY<br>FLUIDS AND<br>TISSUES (cont'd)  | Histopathology examination activities for<br>the purpose of clinical diagnosis (cont'd) | Documented in-house methods  |                  |
| Formalin fixed tissue samples   | X-Ray imaging   | Faxitron PathVision  |                  |
| Bone specimens  | Dissection of bone specimens  | Exact bone saw   | А                |
| Processed tissue samples  |   | Tissue embedding<br>Leica & Thermo Fisher<br>Embedding centres<br>LP 104 004, LP 120 013, LP<br>120 050 & LP 108 007   | A                |
|   |   | Tissue sectioning (microtomy)  |                  |
| Formalin fixed<br>paraffin embedded<br>routine<br>histopathology, and<br>Neuropathology,                    |   | Leica, Microm & Histocore<br>Biocut Microtomes<br>LP 105 001, LP 105 002<br>LP 108 008   | A                |
| tissues samples<br>Fresh frozen<br>human tissue<br>samples  | Detection of Acetylcholinesterase<br>(AChE) enzyme in paediatric bowel<br>tissue        | Manual staining method<br>AchE using kit.<br>LP 103 013 Acetyl<br>Cholinesterase Staining<br>(Hirschsprung Cases)<br>AChE staining bench<br>version<br><u>Routine staining</u> | A                |
| Formalin fixed<br>paraffin embedded<br>routine<br>histopathology, and<br>Neuropathology,<br>tissues samples | Identification of basophilic and eosinophilic structures                                | Manual hand staining<br>Or automated staining using<br>Dako Coverstainer<br>LEICA XL Autostainer<br>LP 105 023 & LP 105 008<br>using Haematoxylin & Eosin<br>stain             | A                |



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|--|--|--|------------------|
| HUMAN BODY<br>FLUIDS AND<br>TISSUES (cont'd)   | Histopathology examination activities for the purpose of clinical diagnosis (cont'd) | Documented in-house methods  |                  |
|  |  | Special staining   |                  |
| Formalin fixed<br>paraffin embedded<br>routine<br>histopathology, and<br>Neuropathology, | Detection of:  | Manual hand staining (M)<br>or automated staining using<br>Dako Artisan Link Pro (A)<br>LP 106 048<br>using stain: | A                |
| tissues samples  | Acid Mucopolysaccharides   | Alcian blue (M)<br>LP106 012   |                  |
|  | Acid & neutral mucins  | Alcian Blue/ PAS Stain (A)<br>LP 106 047   |                  |
|  | Calcium deposits   | Alizarin Red Stain (M)<br>LP106 032  |                  |
|  | Amyloid  | Congo Red (A)<br>LP 106 047  |                  |
|  |  |  |                  |
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United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR UK

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|--|---|--|------------------|
| HUMAN BODY<br>FLUIDS AND<br>TISSUES (cont'd)   | Histopathology examination activities for<br>the purpose of clinical diagnosis (cont'd) | Documented in-house<br>methods<br><u>Special staining (cont'd)</u>   |                  |
| Formalin fixed<br>paraffin embedded<br>routine<br>histopathology, and<br>Neuropathology, |   | Manual hand staining (M) or<br>Dako Artisan Link Pro (A)<br>(cont'd) | A                |
| tissues samples  | Elastic tissue fibres, Muscle, collagen   | EVG - Miller's Elastic Tissue<br>Stain (M)<br>LP106 006              |                  |
|  | Mast cells  | Giemsa pH 5.0 (M)<br>LP 106 040                                      |                  |
|  | Gram +/- organisms  | Gram (M)<br>LP 106 019   |                  |
|  | Fungi   | Grocott- Gomori Methenamine<br>Silver (A)<br>LP 106 047              |                  |
|  | Basophilic and eosinophilic structures  | H & E Rapid (M)<br>LP106 001   |                  |
|  | Elastic fibres and connective tissue  | Haematoxylin Van Gieson (M)<br>LP106 003                             |                  |
|  | Basement membranes  | Jones H&E Stain (M)<br>LP 106 009                                    |                  |
|  | Myelin & Nissl substance  | Kluver Barrera Stain (M)<br>LP 120 018                               |                  |
|  | Melanin pigment   | Masson Fontana (M)<br>LP106 025                                      |                  |
|  | Connective tissue   | Masson Trichrome (A)<br>LP 106 047                                   |                  |
|  | Fibrin  | MSB (M)<br>LP106 018   |                  |
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|---|---|--|------------------|
| HUMAN BODY<br>FLUIDS AND<br>TISSUES (cont'd)  | Histopathology examination activities for<br>the purpose of clinical diagnosis (cont'd) | Documented in-house<br>methods<br><u>Special staining (cont'd)</u>   |                  |
| Formalin fixed<br>paraffin embedded<br>routine<br>histopathology, and<br>Neuropathology,<br>tissues samples |   | Manual hand staining (M) or<br>Dako Artisan Link Pro (A)<br>(cont'd) | A                |
|   | Hepatitis B surface antigen   | Orcein (M)<br>LP106 039  |                  |
|   | Elastic fibres  | Orcein Elastic Stain (M)<br>LP106 007                                |                  |
|   | PAS +ve substances eg: glycogen (and cells of pituitary)                                | Periodic Acid Schiff with and<br>without diastase (A)<br>LP 106 047  |                  |
|   | Removal of Glycogen   | Periodic Acid Schiff Diastase<br>(A)<br>LP 106 047                   |                  |
|   | Haemosiderin and ferric iron  | Perls Prussian Blue (A)<br>LP 106 047                                |                  |
|   | Removal of melanin pigment  | Melanin Bleach (M)<br>LP106 026                                      |                  |
|   | Reticulin   | Untoned Reticulin method -<br>Gordon & Sweets (A)<br>LP 106 047      |                  |
|   | Reticulin   | Toned Reticulin Method (M)<br>LP 106 008                             |                  |
|   | Copper  | Rhodanine Stain (M)<br>LP106 030                                     |                  |
|   | Mycobacterium Leprae  | Wade-Fite (Modified ZN) (M)<br>LP106 022                             |                  |
|   | Helicobacter pylori   | Warthin-Starry Stain (A)<br>LP 106 047                               |                  |



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

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|--|---|--|------------------|
| HUMAN BODY<br>FLUIDS AND<br>TISSUES (cont'd)   | Histopathology examination activities for<br>the purpose of clinical diagnosis (cont'd) | Documented in-house methods (cont'd).                                    |                  |
| Formalin fixed<br>paraffin embedded<br>routine<br>histopathology, and<br>Neuropathology, |   | Manual hand staining (M) or<br>Dako Artisan Link Pro (A)<br>(cont'd)     | A                |
| tissues samples  | Tubercle bacilli (TB)   | Ziehl-Neelsen (M)<br>LP 106 021  |                  |
|  |   | Immunocytochemistry  |                  |
| Paraffin tissue<br>sections of routine<br>histopathology, and<br>Neuropathology,         | Detection of:   | Dako Autostainer Link 48<br>LP 130 007 & LP 130 027<br>using antibodies: | A                |
| tissue samples   | Hepatic Tumours, histocytes   | A-1-antitrypsin  |                  |
|  | Hepatocytes & germ cell tumour  | Alpha foetal protein   |                  |
|  | Secondary Amyloid   | AMYLOID A  |                  |
|  | Amyloid purified protein  | Beta APP   |                  |
|  | Placenta and in certain trophoblastic tumors  | Beta HCG   |                  |
|  | GI tumours / Pancreas   | Ca19-9   |                  |
|  | Thyroid C cella and carcinoma   | Calcitonin   |                  |
|  | Thymoma, T cell malignancies –<br>lymphoma/leukemia                                     | CD1a   |                  |
|  | T and B cells - leukemia  | CD5  |                  |
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United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR UK

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|---|---|--|------------------|
| HUMAN BODY<br>FLUIDS AND<br>TISSUES (cont'd)  | Histopathology examination activities for<br>the purpose of clinical diagnosis (cont'd) | Documented in-house<br>methods<br><u>Immunocytochemistry</u>             |                  |
| Formalin fixed<br>paraffin embedded<br>routine<br>histopathology, and<br>Neuropathology,<br>tissues samples<br>(cont'd) | Detection of (cont'd):  | Dako Autostainer Link 48<br>LP 130 007 & LP 130 027<br>using antibodies: | A                |
|   | B Cells   | CD19   |                  |
|   | Neuroectodermal cells & tumour  | CD57 (NK-1)  |                  |
|   | T & B Cells   | CD45 (LCA, PD7-2B11)   |                  |
|   | Ductal and glandular epithelium   | СК19   |                  |
|   | B cells, lymphatic endothelium  | D2-40  |                  |
|   | Hairy cell leukaemia  | DBA44  |                  |
|   | Gastrointestinal stromal tumour   | DOG1   |                  |
|   | Endothelial cells and megakaryocytes  | FACTOR 8 (Von Willebrand Factor)   |                  |
|   | Blood proenzyme- platelets, histocytes, megakaryocytes                                  | FACTOR 13a   |                  |
|   | Breast ca   | GCDFP-15 Gross cystic<br>disease fluid protein                           |                  |
|   |   |  |                  |
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|--|---|--|------------------|
| HUMAN BODY<br>FLUIDS AND<br>TISSUES (cont'd)   | Histopathology examination activities for<br>the purpose of clinical diagnosis (cont'd) | Documented in-house<br>methods<br><u>Immunocytochemistry</u>             |                  |
| Paraffin tissue<br>sections of routine<br>histopathology, and<br>Neuropathology,<br>tissue samples<br>(cont'd) | Detection of (cont'd):  | Dako Autostainer Link 48<br>LP 130 007 & LP 130 027<br>using antibodies: | A                |
|  | Hepatocytes   | Hepatocyte   |                  |
|  | Herpes simplex virus  | HSV  |                  |
|  | IgG4 plasma cells, IgG4 disease   | lgG4   |                  |
|  | Renal immunoglobulin  | IgA  |                  |
|  | Renal immunoglobulin  | lgD  |                  |
|  | Renal immunoglobulin  | IgG  |                  |
|  | Renal immunoglobulin  | lgM  |                  |
|  | Sex cord stromal tumours  | INHIBIN  |                  |
|  | Mast Cells  | Mast Cell Trypase (MCT)  |                  |
|  | Skeletal muscle   | MYOGENIN   |                  |
|  | DNA mismatch repair enzyme  | MLH1   |                  |
|  | DNA mismatch repair enzyme  | MSH2   |                  |
|  | DNA mismatch repair enzyme  | MSH6   |                  |
|  | Nuclei of myoblasts, fetal muscle   | MYO D1   |                  |
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|--|---|---|------------------|
| HUMAN BODY<br>FLUIDS AND<br>TISSUES (cont'd)                                     | Histopathology examination activities for<br>the purpose of clinical diagnosis (cont'd) | Documented in-house<br>methods  |                  |
| Paraffin tissue<br>sections of routine<br>histopathology, and<br>Neuropathology, | Detection of (cont'd):  | Immunocytochemistry<br>Dako Autostainer Link 48<br>LP 130 007 & LP 130 027<br>using antibodies: | A                |
| tissue samples<br>(cont'd)   | Nuclei of myoblasts, fetal muscle   | Myogenin  |                  |
|  | Neuroendocrine tissues  | Neurofilament protein   |                  |
|  | Neuroblastoma   | NB84  |                  |
|  | Neutophils  | NP57  |                  |
|  | Glandular epithelium in prostate  | PAP   |                  |
|  | Nuclear component over-expressed in some tumours  | P53   |                  |
|  | Activated T-cells   | PDL1  |                  |
|  | Non-small cell lung Ca, urothelial Ca, head and neck squamous cell Ca                   | PD-L1 (22C3)  |                  |
|  | Head and neck squamous cell Ca, melanoma  | PD-L1 (28-8)  |                  |
|  | Protein in neuroendocrine cell+s  | PGP9.5  |                  |
|  | Germ cell tumours   | PLAP  |                  |
|  | DNA mismatch repair enzyme  | PMS2  |                  |
|  | Smooth muscle myosin  | SMMS-1  |                  |
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|--|---|---|------------------|
| HUMAN BODY<br>FLUIDS AND<br>TISSUES (cont'd)   | Histopathology examination activities for<br>the purpose of clinical diagnosis (cont'd) | Documented in-house methods   |                  |
|  |   | Immunocytochemistry   |                  |
| Paraffin tissue<br>sections of routine<br>histopathology, and<br>Neuropathology,<br>tissue samples | Detection of (cont'd):  | Dako Autostainer Link 48<br>LP 130 007 & LP 130 027<br>using antibodies:  | A                |
| (cont'd)   | Yolk sac tumour   | SALL 4  |                  |
|  | T and B cells in leukaemia  | TDT   |                  |
|  |   | Immunocytochemistry   |                  |
| Paraffin tissue<br>sections of routine<br>histopathology, and<br>Neuropathology,<br>tissue samples | Detection of  | Documented in-house<br>procedures LP 130 007 & LP<br>130 029 in conjunction with<br>manufacturers instructions<br>using Dako Omnis and<br>antibodies: | A                |
|  | Epithelial cells  | AE1/AE3   |                  |
|  | Lymphomas   | ALK 1   |                  |
|  | Prostate Ca   | AMACR   |                  |
|  | Smooth muscle, myofibroblasts, myoepithelial cells                                      | ASMA  |                  |
|  | Prostate  | 34 BE12   |                  |
|  | Cytoplasmic Protein   | Beta Catenin  |                  |
|  | Scattered T cells in germinal centres and mantle zone B cells-follicular lymphoma       | BCL2  |                  |
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|--|---|---|------------------|
| HUMAN BODY<br>FLUIDS AND<br>TISSUES (cont'd)   | Histopathology examination activities for<br>the purpose of clinical diagnosis (cont'd) | Documented in-house methods   |                  |
|  |   | Immunocytochemistry   |                  |
| Paraffin tissue<br>sections of routine<br>histopathology, and<br>Neuropathology,<br>tissue samples<br>(cont'd) | Detection of (cont'd)   | Documented in-house<br>procedures LP 130 007 & LP<br>130 029 in conjunction with<br>manufacturers instructions<br>using Dako Omnis and<br>antibodies: | A                |
|  | lymphoma  | BCL 6   |                  |
|  | Mesothelioma panel marker epithelial  | BEREP4  |                  |
|  | B cells in lymphoma   | BSAP (PAX5)   |                  |
|  | Ovarian tumours   | CA125   |                  |
|  | Smooth muscle and sarcoma   | CALDESMON   |                  |
|  | Mesothelial and lung tumours  | CALRETININ  |                  |
|  | Pan t-lymphocytes   | CD2   |                  |
|  | T cells in mantle zone  | CD3   |                  |
|  | T cells   | CD4   |                  |
|  | T cells   | CD8   |                  |
|  | T cell malignancy   | CD7   |                  |
|  | Childhood ALL, follicular lymphoma  | CD10  |                  |
|  | Reed Sternberg cells, hodgkins and meso panel   | CD15 Leu M1   |                  |
|  | B cells-lymphoma  | CD20  |                  |
|  | B cells- dendritic cells  | CD21  |                  |
|  | Lymphocytes in germinal centres   | CD23  |                  |
|  | Reed Sternberg cells, hodgkins  | CD30 (Ki1)  |                  |
|  | Endothelial cells- malignancy   | CD31  |                  |



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|--|--|---|------------------|
| HUMAN BODY<br>FLUIDS AND<br>TISSUES (cont'd)   | Histopathology examination activities for the purpose of clinical diagnosis (cont'd) | Documented in-house methods   |                  |
|  |  | Immunocytochemistry   |                  |
| Paraffin tissue<br>sections of routine<br>histopathology, and<br>Neuropathology,<br>tissue samples<br>(cont'd) | Detection of (cont'd)  | Documented in-house<br>procedures LP 130 007 & LP<br>130 029 in conjunction with<br>manufacturers instructions<br>using Dako Omnis and<br>antibodies: | A                |
|  | Vascular epithelium  | CD34 (Q bend/10)  |                  |
|  | T cell lymphoma  | CD43  |                  |
|  | Neuroectodermal cells, neurones, astrocytes  | CD56  |                  |
|  | Megakaryocyes in trephines   | CD61  |                  |
|  | Macrophages  | CD68  |                  |
|  | B cells  | CD79a   |                  |
|  | Ewings sarcoma   | CD99 (MIC2)   |                  |
|  | GIST tumours   | CD117 (c-kit)   |                  |
|  | B lymphocyte differentiation   | CD138   |                  |
|  | Differentiation of carcinoids and metastatic adeno Ca                                | CDX-2   |                  |
|  | Neuroendocrine cells   | CHROMOGRANIN  |                  |
|  | Squamous cell carcinoma  | P40   |                  |
|  | T and B cells - Leukemia   | CD5   |                  |
|  | prostate   | СК5/6   |                  |
|  | ovarian  | CK7   |                  |
|  | Cytoskeleton, epithelial cells   | CK8/18  |                  |
|  | Cytoskeleton, epithelial cells   | CK14  |                  |
|  | ovarian  | СК20  |                  |
|  |  |   |                  |



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

#### **University Hospitals Southampton NHS Foundation Trust**

Issue No: 006 Issue date: 06 February 2024

| Materials/Products<br>tested   | Type of test/Properties measured/Range<br>of measurement                                | Standard specifications/<br>Equipment/Techniques used   | Location<br>Code |
|--|---|---|------------------|
| HUMAN BODY<br>FLUIDS AND<br>TISSUES (cont'd)   | Histopathology examination activities for<br>the purpose of clinical diagnosis (cont'd) | Documented in-house methods   |                  |
|  |   | Immunocytochemistry   |                  |
| Paraffin tissue<br>sections of routine<br>histopathology, and<br>Neuropathology,<br>tissue samples<br>(cont'd) | Detection of (cont'd)   | Documented in-house<br>procedures LP 130 007 & LP<br>130 029 in conjunction with<br>manufacturers instructions<br>using Dako Omnis and<br>antibodies: | A                |
|  | mantle cell lymphoma  | CYCLIN D1   |                  |
|  | Cytomegalovirus   | CMV   |                  |
|  | Smooth and striated muscle  | DESMIN  |                  |
|  | Epithelial cell Ca  | E-CADHERIN  |                  |
|  | Epithelial cells  | EMA   |                  |
|  | Glial fibrillary acide protein  | GFAP  |                  |
|  | Red blood cells & their precursors  | Glycophorin   |                  |
|  | Melanocytes   | HMB 45  |                  |
|  | Glial tumours   | IDH-1   |                  |
|  | Proliferating cells   | Ki67 (MIB1)   |                  |
|  | Kappa immunoglobulin light chain  | Карра   |                  |
|  | Kappa immunoglobulin light chain optimised for BMTs                                     | КВМТ  |                  |
|  | Lambda immunoglobulin light chain   | Lambda  |                  |
|  | Lambda immunoglobulin light chain optimised for BMTs                                    | LBMT  |                  |
|  | Melanocytes   | MELAN A   |                  |
|  |   |   |                  |
|  |   |   |                  |



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| HUMAN BODY<br>FLUIDS AND<br>TISSUES (cont'd)<br>Paraffin tissue<br>sections of routine<br>histopathology, and<br>Neuropathology,<br>tissue samples<br>(cont'd) | Histopathology examination activities for<br>the purpose of clinical diagnosis (cont'd)<br>Detection of (cont'd)<br>b cell lymphoma | Documented in-house<br>methods<br><u>Immunocytochemistry</u><br>Documented in-house<br>procedures LP 130 007 & LP<br>130 029 in conjunction with<br>manufacturers instructions<br>using Dako Omnis and<br>antibodies:<br>MUM-1 | A                |
|  | Cytokeratin cocktail  | MNF116   |                  |
|  | Granulocytes & monocytes  | Myeloperoxidase  |                  |
|  | Myoepithelial cells   | P63  |                  |
|  | Breast epithelium   | Progesterone Receptor (PR)   |                  |
|  | Prostate neoplasm   | PSA  |                  |
|  | Renal cell ca   | RCC  |                  |
|  | Melanoma, glial cells   | S100   |                  |
|  | Yolk sac tumour   | SALL 4   |                  |
|  | Signal transducer and activator of transcription 6  | STAT6  |                  |
|  | Protein in neuroendocrine cells   | Synaptophysin  |                  |
|  | Lung and thyroid  | TTF-1  |                  |
|  | Renal tumours, mesothelioma   | WT1  |                  |
|  |   |  |                  |



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| HUMAN BODY<br>FLUIDS AND<br>TISSUES (cont'd)  | Histopathology examination activities for the purpose of clinical diagnosis (cont'd)  | Documented in-house methods  |                  |
|   |   | In-situ Hybridisation  |                  |
| Paraffin tissue section   | Detection of:   | Ventana BenchMark Ultra<br>LP 130 007 & LP 130 022<br>using antibodies/probes:   | А                |
|   | HER2 receptors/gene   | HER2-ICC   |                  |
|   | Epstein-Barr Virus  | EBER-ISH   |                  |
|   | Human papillomavirus positive cancer  | HPV-ISH  |                  |
|   |   | Immunocytochemistry  |                  |
|   | Detection of:   | Documented in-house<br>procedures LP 130 007 & LP<br>130 022 in conjunction with<br>manufacturers instructions<br>using Ventana BenchMark<br>Ultra and antibodies: |                  |
|   | Non-small cell lunch Ca   | ALK D5F3   |                  |
|   | Oestrogen Recepton  | ER   |                  |
|   | Breast Ca, urothelial Ca  | GATA3  |                  |
|   | Cervical Ca, head and neck Ca   | P16  |                  |
|   | Epithelial cells and carcinoma  | PAX-8  |                  |
|   | Triple negative breast Ca, urothelial Ca  | PD-L1 SP142  |                  |
|   | Melanoma  | SOX 10   |                  |
|   | Expression pf ROS1 fusion protein   | ROS1   |                  |
|   |   | Immunocytochemistry  |                  |
| Paraffin sections of<br>routine<br>histopathology, and<br>Neuropathology,<br>tissue samples | Microscopic interpretation of thin tissue<br>sections stained by manual<br>immunohistochemical (IHC) techniques to<br>demonstrate specific tissue components to<br>aid diagnosis for the purposes of disease<br>identification: | Manual hand staining<br>LP 120 026<br>using antibodies:  | A                |



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| HUMAN BODY<br>FLUIDS AND<br>TISSUES (cont'd)             | Histopathology examination activities for<br>the purpose of clinical diagnosis (cont'd)           | Documented in-house methods  |                  |
|  | Alzheimers amyloid  | Beta-Amyloid   |                  |
| Slides prepared in<br>house from samples<br>listed above | Morphological assessment and interpretation/diagnosis   | <u>Qualitative Microscopy</u><br>Nikon bright field microscopes<br>TP 000 005  | A                |
| Fresh frozen<br>human skin tissue<br>samples             | Frozen section analysis of human<br>tissue samples to aid in clinical<br>assessment and diagnosis | Skin samples frozen and embedded using Prestochill flash chiller.  | D                |
|  |   | Frozen sections cut on the Leica CM1950 cryostat   |                  |
|  |   | Frozen section slides<br>stained using the Presto<br>Pro automated staining<br>platform.   |                  |
|  |   | Slides analysed using<br>Nikon microscope- model<br>eclipse Ci-L   |                  |
|  |   | Measurement principle:<br>analysis of tissue for<br>presence/absence of Basal<br>cell carcinoma in skin<br>samples.<br>Procedure allows analysis<br>of 100% of the margins.                        |                  |
|  |   | LP Mohs 006- SAMPLE<br>COLLECTION SOP<br>LP MOHS 003-Mohs<br>SAMPLE PREP-<br>EMBEDDING SOP<br>LP MOHS 004- Cryotomy<br>LP MOHS 005- Staining of<br>MOHs slides on the Presto<br>Pro<br>LP MOHS 002 |                  |
|  |   | Maintenance of Mohs lab  |                  |



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| HUMAN BODY<br>FLUIDS AND<br>TISSUES (cont'd)   | Diagnostic Cytopathology   |   |                  |
| Air-dried aspirated<br>and voided human<br>body fluids, fine<br>needle aspirates<br>(FNA's) and<br>brushings.  | Examination of cell preparations to identify<br>or exclude cytological abnormalities for the<br>purposes of diagnosis. | Preparation of slides<br>Cytospin 4<br>LP 220 012 & LP 220 013<br>LP 108 014<br>LP120 019<br>Manual staining: | A                |
| Cytological smear preparations   |  | LP 220 006<br>Using stain:<br>Romanowsky stain  | A                |
| Cytological Brushing<br>slide preparations,<br>Fine needle aspirate<br>slide preparations  |  | Romanowsky stain  | A, B & C         |
| Cytological smear<br>preparations,<br>Sputum slide<br>preparations,<br>Body fluid slide<br>preparations,<br>Brushing slide<br>preparations,<br>Fine needle aspirate<br>slide preparations,<br>Bronchial Lavage<br>slide preparations |  | Automated staining<br>Leica Autostainer XL<br>LP220 003<br>using Papanicolaou stain                           | A                |
| Unstained wet-<br>preparations of<br>synovial fluid<br>samples   | Examination of Crystals in Synovial Fluid<br>(M)   | Qualitative Microscopy<br>Nikon bright field microscopes<br>TP 000 005  | A                |
| Wet-fixed aspirated<br>and voided human<br>body fluids, fine<br>needle aspirates<br>(FNA's) & brushings  | Examination of cell preparations to identify<br>or exclude cytological abnormalities for the<br>purposes of diagnosis. | Production of cell block<br>Manual preparation of cell<br>blocks using "Cytoblock Kit"<br>LP 220 018          | A                |



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| HUMAN BODY<br>FLUIDS AND<br>TISSUES (cont'd)                                      | <u>Cytopathology examination activities for the</u><br>purpose of clinical diagnosis (cont'd)  | Documented in-house<br>methods   |                  |
| Slides prepared in<br>house from samples<br>listed above                          | Morphological assessment and interpretation/diagnosis  | <u>Qualitative Microscopy</u><br>Nikon bright field microscopes<br>TP 000 005  | A                |
|   | Electron microscopy examination activities<br>for the purpose of clinical diagnosis  | Documented in-house methods  |                  |
|   | Electron Microscopy  |  |                  |
| Glutaraldehyde fixed<br>nasal and bronchial<br>brushing samples                   | Electron Microscopy for PCD diagnosis<br>Demonstration of ultrastructural<br>components of ciliated epithelial cells   | Preparation of samples for<br>Electron Microscopy for PCD<br>diagnosis, including fixation,<br>dehydration, infiltration with<br>resin of tissue samples.<br>Cutting thick survey sections,<br>staining and assessment of<br>thick sections. Cutting and<br>staining thin sections using<br>Documented in-house<br>procedures<br>LP 400 026, LP 400 050, LP<br>400 020, LP 400 033, LP 400<br>032, LP 400 013, LP 400 027,<br>LP 400036 using Reichert and<br>Ultracut Ultramicrotomes | A                |
| Glutareldehyde<br>Fixed Resin<br>Embedded Tissue<br>sections prepared as<br>above | Morphological assessment and<br>interpretation including quantification of<br>defects in ciliary structure<br>contributing to diagnosis of PCD.<br>Production of micrographs suitable for<br>diagnostic use. | Counting and analysing cilia in<br>nasal and bronchial brushings<br>for PCD (Primary Ciliary<br>Dyskinesia) diagnosis, using<br>Documented in-house<br>procedures LP 400 057,<br>LP400 031, LP 400 010 & LP<br>400 055 in conjunction with<br>manufacturers instructions for<br>staining using FEI Tecnai TEM<br>and Hitachi H7700 TEM   | A                |



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| HUMAN BODY<br>FLUIDS AND<br>TISSUES (cont'd)                                      | Electron microscopy examination activities<br>for the purpose of clinical diagnosis<br>Routine Diagnostic Electron Microscopy   | Documented in-house<br>methods   |                  |
| Formalin and<br>glutaraldehyde fixed<br>tissue samples                            | Demonstration of ultrastructural<br>components of renal, muscle, nerve and<br>other tissues.<br>Production of micrographs suitable for<br>diagnostic use by Biomedical Imaging staff<br>and their interpretation by consultant<br>pathologists. | Receiving and Preparing<br>diagnostic Specimens for EM<br>Processing including fixation,<br>dehydration, infiltration with<br>resin of tissue samples.<br>Cutting thick survey sections,<br>staining and assessment of<br>thick sections. Cutting and<br>staining thin sections, using<br>Documented in-house<br>procedures LP 400 050, LP<br>400 020, LP 400 033, LP 400<br>032, LP 400 013, LP 400 027<br>& LP 400 036 in conjunction<br>with manufacturers<br>instructions for staining using<br>Reichert and Ultracut<br>Ultramicrotomes | Α                |
| Glutareldehyde<br>Fixed Resin<br>Embedded Tissue<br>sections prepared as<br>above | Morphological assessment and<br>interpretation.<br>Production of micrographs suitable for<br>diagnostic use by Biomedical Imaging staff<br>and their interpretation by consultant<br>pathologists.  | Taking Diagnostic TEM<br>photographs, using<br>Documented in-house<br>procedures LP400 031, LP<br>400 010 & LP 400 055 in<br>conjunction with<br>manufacturer's instructions<br>using FEI Tecnai 12 TEM and<br>Hitachi H7700 TEM   | A                |
|   | END   |  |                  |