### **Schedule of Accreditation**

issued by

### **United Kingdom Accreditation Service**

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



7924

Accredited to ISO 15189:2022

### **Liverpool University Hospitals NHS Foundation Trust**

Issue No: 010 Issue date: 15 April 2025

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L7 8YE E-Mail: Ines.Santos@liverpoolft.nhs.uk

United Kingdom Website: www.liverpoolcl.nhs.uk/

Testing performed by the Organisation at the locations specified below

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

### **Laboratory locations:**

| Location details   |  | Activity   | Location code |
|--|--|--|---------------|
| Address Clinical Sciences Services Building Royal Liverpool Hospital Liverpool University Hospitals Foundation Trust Mount Vernon Street Liverpool L7 8YE United Kingdom | Local contact James Wingfield 0151 706 2000 james.wingfield@liverpoolft.nhs.uk | Diagnostic cytology(non-Gynae) Special Stains Immunocytochemistry Routine Histopathology Frozen Section Histology Immunofluorescence Molecular Pathology Mortuary Services (body receipt, storage and release) | A             |

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

| Location details  |  | Activity   | Location code |
|---|--|--|---------------|
| Address FNA Clinic Aintree Hospital Longmoor Lane Liverpool L9 7AL                        | Local Contact Claire Chadwick 0151 706 5623 claire.chadwick@liverpool.nhs.uk           | FNA slide preparation, adequacy assessment and reporting | В             |
| Address Mortuary Royal Liverpool University Hospital Mount Vernon Street Liverpool L7 8YE | Local Contact<br>Neil White<br>0151 706 3801<br>neil.white@liverpoolft.nhs.uk          | Mortuary Services (body receipt, storage and release)    | A             |
| Address Mortuary Aintree University Hospital Lower Lane Liverpool L9 7AL                  | Local Contact<br>Neil White – as above   | Body storage   | С             |
| Address Mortuary Broadgreen Hospital Thomas Drive Liverpool L14 3LB                       | Local Contact<br>Neil White – as above   | Body storage   | D             |
| Address Theatres Royal Liverpool University Hospital Prescot Street Liverpool L7 8XP      | Local Contact<br>Georgio Bristol<br>0151 706 4677<br>georgio.bistol.liverpoolft.nhs.uk | Renal sample adequacy check.                             | Е             |

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### **DETAIL OF ACCREDITATION**

| Materials/Products tested   | Type of test/Properties measured/Range of measurement  | Standard specifications/<br>Equipment/Techniques used  | Location<br>Code |
|---|--|--|------------------|
| HUMAN TISSUES AND FLUIDS  | Diagnostic Cytology  |  |                  |
| CSF, urine, general body<br>fluids, bronchial brushings,<br>EBUS, ERCP      | Preparation and examination of cellular material to identify or exclude morphological and cytological abnormalities. | In-house documented procedures using:  Preparation of cell samples Sakura Cyto-Tek Centrifuge Thermoscientific centrifuge CP-NCER-SOP-23 Genesis T200 slide processor and Leica ST5020 Multistainer and CV5030 Coverslipper CP-NCER-SOP-4 CP-NCER-SOP-5 Preparation of fluids requiring cytospin CP-NCER-SOP-1 Fine needle aspiration cytology  Fluid preparation using Holigic thin prep CP-NCER-SOP-11 | A                |
|   |  | Production of cell block CP-NCER-SOP-10 Preparation of an Agar Cell Block  | А                |
| CSF, urine, general body<br>fluids, bronchial brushings,<br>EBUS, ERCP, FNA | Preparation and examination of cellular material to identify or exclude morphological and cytological abnormalities. | Staining In-house procedures using Leica stainer ST5020 and May Grunwald Giemsa stain CP-NCER-SOP-4 CP-NCER-SOP-2 May Grunwald Giemsa method   | А                |
| FNA   | Morphological assessment in order to ascertain adequacy for diagnosis and interpretation/diagnosis                   | Material/slide preparation and staining May Grunwald stain CP-NCER-SOP-2 and CP-NCER-SOP-1 Fine needle aspiration cytology   | В                |
| CSF, urine, general body<br>fluids, bronchial brushings,<br>EBUS, ERCP, FNA |  | Interpretive Microscopy Non cervical cytology reporting Guidelines CP-NER-SOP-15   | А                |

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|---|---|--|------------------|
| HUMAN BODY TISSUE<br>SAMPLES  | Histopathological examination activities for the purposes of clinical diagnosis | In house documented procedures using manual methods or analysers in conjunction with manufacturer's instructions for the following methods (where relevant):   | А                |
| Fixed, fresh and frozen tissue; excisional and incisional biopsies and surgical resection specimens |   | Specimen dissection: Envair Downdraft tables  Handling of ocular referral specimens form external HM Coroner and Police forces CP-OPAT-SOP-10  Routine Bone decalcification CP-SPE-SOP-20  Tissue processing:  Leica Peloris II Automated tissue processor CP-HIS-SOP-53  Leica Peloris III automated tissue processor CP-HIS-SOP-76 |                  |
| Formalin Fixed Paraffin wax blocks of processed tissue.   |   | Embedding: Thermo Histostar CP-HIS-SOP-8  Microtomy: Leica RM2255 automated microtomes CP-HIS-SOP-17   |                  |

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| HUMAN BODY TISSUE<br>SAMPLES (cont'd)  | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | In house documented procedures using manual methods or analysers in conjunction with manufacturer's instructions for the following methods (where relevant): | А                |
| Tissue for frozen sections   |  | Cryotomy Intra-operative Frozen section Leica CM1850 UV Leica CM 1860 UV CP-HIS-SOP-27   |                  |
| FFPE slides<br>(Formalin fixed paraffin<br>embedded) tissue on glass<br>slides and frozen sections |  | Interpretive/diagnostic microscopy<br>CP-PATH-POL-2  |                  |
|  | Morphological staining For the detection of:   |  |                  |
|  | Basophilic and eosinophilic structures   | Routine morphological staining using Tissue tek Prisma Stained and Tissue Tek Glas coverslipper CP-HIS-SOP-24  |                  |
|  |  | Haematoxylin and Eosin (H & E)<br>manual stain CP-HIS-SOP-9  |                  |
| FFPE slides<br>(Formalin fixed paraffin<br>embedded) tissue on glass                               | Special stains for the detection of:   |  |                  |
| slides   | Acid and neutral mucopolysaccharides, glycogen and fungi                                 | Diastase Alcian Blue Periodic acid<br>Schiffs (DABPAS) (ABPAS)<br>CP-HIS-SOP-43  |                  |
|  | Acid and Neutral<br>Mucopolysaccharides  | Alcian Blue<br>CP-HIS-SOP-61   |                  |
|  | Microorganisms and haemopoietic cells  | Geimsa<br>CP-HIS-SOP-44  |                  |
|  | Connective tissue  | Gomori's trichrome (one stage)<br>CP-HIS-SOP-45  |                  |
|  | Fibrin   | Martius Scarlet Blue (MSB)<br>CP-HIS-SOP-46  |                  |

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| HUMAN BODY TISSUE<br>SAMPLES (cont'd)                          | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | In house documented procedures using manual methods or analysers in conjunction with manufacturer's instructions for the following methods (where relevant): | А                |
| FFPE slides (Formalin fixed paraffin embedded) tissue on glass | Special stains for the detection of: (cont'd)  |  |                  |
| slides (cont'd)  | Reticulin  | Gordon and Sweets<br>CP-HIS-SOP-47   |                  |
|  | Spirochaetes   | Steiner<br>CP-HIS-SOP-48   |                  |
|  | Mast cells   | Toluidine Blue<br>CP-HIS-SOP-50  |                  |
|  | Amyloid  | Congo red<br>CP-HIS-SOP-2  |                  |
|  | Leprosy  | Fite-Faraco<br>CP-HIS-SOP-3  |                  |
|  | Bacteria   | Gram<br>CP-HIS-SOP-4   |                  |
|  | Fungi  | Grocott Silver<br>CP-HIS-SOP-28  |                  |
|  | Connective tissue  | Haematoxylin Van Gieson (HVG)<br>CP-HIS-SOP-22   |                  |
|  | Basement membranes   | Jones methanamine silver<br>CP-HIS-SOP-23  |                  |
|  | Argentaffin cells, melanin   | Masson Hamperl<br>CP-HIS-SOP-30  |                  |
|  | Connective tissue  | Masson Trichrome<br>CP-HIS-SOP-107   |                  |
|  | Melanin  | Melanin bleach<br>CP-HIS-SOP-31  |                  |
|  |  |  |                  |

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| HUMAN BODY TISSUE<br>SAMPLES (cont'd)   | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | In house documented procedures using manual methods or analysers in conjunction with manufacturer's instructions for the following methods (where relevant): | А                |
| FFPE slides<br>(Formalin fixed paraffin<br>embedded) tissue on glass<br>slides (cont'd) | Special stains for the detection of: (cont'd)  |  |                  |
| slides (cont d)   | Elastin  | Millers Elastic Van Gieson (EVG)<br>CP-HIS-SOP-21  |                  |
|   | Haemosiderin and ferric iron   | Perls<br>CP-HIS-SOP-5  |                  |
|   | Hep B Sag and copper associated protein  | Shikata Orcein<br>CP-HIS-SOP-32  |                  |
|   | Calcium  | Van Kossa<br>CP-HIS-SOP-51   |                  |
|   | Tubercle bacilli   | Ziehl Neelson<br>CP-HIS-COP-6  |                  |
| Formalin fixed lung tissue on glass slide   | Asbestos fibres  | Post mortem Asbestos Fibre Count<br>CP-SPE-SOP-31  |                  |
| FFPE slides<br>(Formalin fixed paraffin<br>embedded) tissue on glass                    | Immunohistochemistry to detect the following:  | Immunocytochemistry Dako Omnis<br>Basic User SOP: CP-IMM-SOP-33  |                  |
| slides, cell blocks and<br>formalins fixed cytospins<br>slides                          |  | Immunocytochemistry Dako Omnis<br>Advanced User: CP-IMM-SOP-36   |                  |
| silues  |  | Immunocytochemistry Use of Dako<br>Coverslipper: CP-IMM-SOP-18   |                  |
|   |  | Interpretive Microscopy procedures: Pathologist Reporting and Cut-up: CP-PATH-POL-2 and PD-L1 Reporting Procedures: CP-PATH-POL-6                            |                  |
|   | High molecular weight cytokeratins   | 34BE12   |                  |
|   | A1AT deficiency  | A1AT (Alpha 1 Anti-trypsin)  |                  |

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| HUMAN BODY TISSUE<br>SAMPLES (cont'd)  | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | In house documented procedures using manual methods or analysers in conjunction with manufacturer's instructions for the following methods (where relevant):  | А                |
| FFPE slides (Formalin fixed paraffin embedded) tissue on glass slides, cell blocks and formalins fixed cytospins slides (cont'd) | Immunohistochemistry to detect the following: (cont'd)                                   | Immunocytochemistry Dako Omnis Basic User SOP: CP-IMM-SOP-33  Immunocytochemistry Dako Omnis Advanced User: CP-IMM-SOP-36  Immunocytochemistry Use of Dako Coverslipper: CP-IMM-SOP-18  Interpretive Microscopy procedures: Pathologist Reporting and Cut-up: CP-PATH-POL-2 and PD-L1 Reporting Procedures: CP-PATH-POL-6 |                  |
|  | Pan-cytokeratin  | AE1AE3  |                  |
|  | Androgen receptor in prostate and breast tumours   | AR (Androgen Receptor)  |                  |
|  | B-Catenin protein in fibromatous lesions   | B-CAT (Beta catenin)  |                  |
|  | BRCA associated protein  | BAP-1 (BRCA associated protein)   |                  |
|  | Diffuse lymphoproliferative disease and neoplastic cells of follicular lymphomas         | BCL-2   |                  |
|  | Germinal centre B-lymphs   | BCL-6   |                  |
|  | Epithelial cell types  | BEREP4  |                  |
|  | Ovarian tumour marker  | CA125   |                  |
|  | Parafollicular cells in thyroid and medullary thyroid carcinoma                          | Calcitonin  |                  |
|  | Marker of smooth muscle  | Caldesmon   |                  |
|  | Marker of mesothelioma   | Calretinin  |                  |

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|  | Epithelial marker  | CAM 5.2   |                  |
|  | Langerhan's cells and interdigitating reticulum cells                                    | CD1a  |                  |
|  | Peripheral T-Lymphocytes   | CD2   |                  |
|  | T-Lymphocytes  | CD3   |                  |
|  | Germinal centre T lymphocytes and B lymphocyte subset                                    | CD5   |                  |
|  | Suppressor/cytotoxic T-cells   | CD8   |                  |
|  | Lymphoid and endometrial malignancies  | CD10  |                  |
|  | Reed-Sternberg cells, myeloid cells and epithelial cells                                 | CD15  |                  |
|  | Normal and neoplastic B-cells  | CD20  |                  |
|  | Hodgkins and Reed Sternberg cells, ALCL and embryonal carcinoma                          | CD30  |                  |

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| FFPE slides (Formalin fixed paraffin embedded) tissue on glass slides, cell blocks and formalins fixed cytospins slides (cont'd) | Immunohistochemistry to detect the following: (cont'd)                                   | Immunocytochemistry Dako Omnis Basic User SOP: CP-IMM-SOP-33  Immunocytochemistry Dako Omnis Advanced User: CP-IMM-SOP-36  Immunocytochemistry Use of Dako Coverslipper: CP-IMM-SOP-18  Interpretive Microscopy procedures: Pathologist Reporting and Cut-up: CP-PATH-POL-2 and PD-L1 Reporting Procedures: CP-PATH-POL-6 |                  |
|  | Endothelial cells  | CD31  |                  |
|  | Endothelial cells and other cell types in various solid tumours                          | CD34  |                  |
|  | Plasma cells   | CD38  |                  |
|  | T-cells and myeloid lineage cells  | CD43  |                  |
|  | Lymphocytes and reactive urothelium  | CD44  |                  |
|  | T and B lymphocytes  | CD45 (Leucocyte common antigen)   |                  |
|  | NK cells, nerves and neuroendocrine differentiation                                      | CD56  |                  |
|  | NK cells   | CD57  |                  |
|  | Megakaryocytes and platelets   | CD61  |                  |
|  | Macrophages, myeloid cells and monocytes   | CD68 (KP1)  |                  |
|  | Macrophages and monocytes  | CD68 (PG)   |                  |

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| FFPE slides<br>(Formalin fixed paraffin<br>embedded) tissue on glass<br>slides, cell blocks and<br>formalins fixed cytospins<br>slides (cont'd) | Immunohistochemistry to detect the following: (cont'd)                                   | Immunocytochemistry Dako Omnis Basic User SOP: CP-IMM-SOP-33  Immunocytochemistry Dako Omnis Advanced User: CP-IMM-SOP-36  Immunocytochemistry Use of Dako Coverslipper: CP-IMM-SOP-18  Interpretive Microscopy procedures: Pathologist Reporting and Cut-up: CP-PATH-POL-2 and PD-L1 Reporting Procedures: CP-PATH-POL-6 |                  |
|   | B lymphocytes  | CD79a   |                  |
|   | Ewing's sarcoma  | CD99  |                  |
|   | Stem cells, melanocytes , mast cells and GIST tumours                                    | CD117 (c-kit)   |                  |
|   | Plasma cells   | CD138   |                  |
|   | Lining of blood and lymphatic vessels and mesothelial cells                              | CD141(thrombomodulin)   |                  |
|   | Intestinal epithelia and GI tract tumours  | CDX2  |                  |
|   | Epithelial marker  | CEA-M (carcinoembryonic antigen)  |                  |
|   | Neuroendocrine cells   | CHROMA (Chromogranin A)   |                  |
|   | Stratified squamous epithelia, basal cells and mesotheliomas                             | Ck5/6 (Cytokeratins 5 & 6)  |                  |
|   | Normal and neoplastic epithelia  | CK7 (Cytokeratin 7)   |                  |
|   | Normal and neoplastic epithelia  | CK19 (Cytokeratin 19)   |                  |

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|  | Normal and neoplastic epithelia  | CK20 (Cytokeratin 20)   |                  |
|  | Cytomegalovirus infection  | CMV   |                  |
|  | Interstitial cells of Cajal in GIT and GIST tumours                                      | DOG-1   |                  |
|  | Lymphatic endothelium  | D2-40 (Podoplanin)  |                  |
|  | Epithelial cell adhesion molecule  | E-CAD (e-cadherin)  |                  |
|  | Normal and neoplastic epithelia  | EMA (Epithelial membrane antigen)   |                  |
|  | Cellular oestrogen receptor expression   | ER (Oestrogen receptor)   |                  |
|  | Apocrine epithelia and breast carcinoma  | GCDFP (Gross cystic disease fluid protein-15)   |                  |
|  | Cytotoxic T lymphocytes and NK cells   | GRANB (Granzyme B)  |                  |
|  | Distinguish mesothelioma from adenocarcinoma and thyroid carcinoma from benign lesions   | HBME-1  |                  |

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|  | HCG in trophoblastic elements and germ cell tumours                                      | HCG (Human chorionic gonadotrophin)   |                  |
|  | Normal and malignant hepatocytes   | НЕРАТО  |                  |
|  | Melanoma and melanocyte differentiation  | HMB45   |                  |
|  | Kaposi's sarcoma and Castleman's disease   | HHV8 (human herpes virus 8)   |                  |
|  | Plasma cells and related lymphoid cells containing IgA                                   | IgA specific for alpha chains   |                  |
|  | Plasma cells and related lymphoid cells containing IgG                                   | IgG specific for gamma chains   |                  |
|  | Plasma cells and related lymphoid cells containing IgM                                   | IgM specific for Mu-chains  |                  |
|  | Sertoli cells, granulosa cell<br>tumours and sex cord stromal<br>tumours                 | INHIB   |                  |
|  |  |   |                  |

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|  | Insulin producing cells in normal and neoplastic tissue                                  | INS   |                  |
|  | Plasma cells and related lymphoid cells containing Kappa light chains                    | KAP   |                  |
|  | Proliferation marker   | Ki67  |                  |
|  | Plasma cells and related lymphoid cells containing Lambda light chains                   | LAM   |                  |
|  | Neoplasms of squamous cell origin, hair follicles and myoepithelial cells                | LLOO2 (cytokeratin 14)  |                  |
|  | Melanoma marker  | MEL-A   |                  |
|  | Melanocytes and retinal pigment epithelium, melanomas and naevi                          | MITF  |                  |
|  | Epithelial marker  | MNF-116   |                  |
|  | Mismatch repair protein  | MSH-2   |                  |
|  | Mismatch repair protein  | MSH6  |                  |

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| HUMAN BODY TISSUE<br>SAMPLES (cont'd)  | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | In house documented procedures using manual methods or analysers in conjunction with manufacturer's instructions for the following methods (where relevant):   | A                |
| FFPE slides (Formalin fixed paraffin embedded) tissue on glass slides, cell blocks and formalins fixed cytospins slides (cont'd) | Immunohistochemistry to detect the following: (cont'd)                                   | Immunocytochemistry Dako Omnis Basic User SOP: CP-IMM-SOP-33  Immunocytochemistry Dako Omnis Advanced User: CP-IMM-SOP-36  Immunocytochemistry Use of Dako Coverslipper: CP-IMM-SOP-18  Interpretive Microscopy procedures: Pathologist Reporting and Cut-up: CP-PATH-POL-2 and PD-L1 Reporting Procedures: CP-PATH- |                  |
|  |  | POL-6  |                  |
|  | Mucin glycoprotein-1   | MUC-1  |                  |
|  | Mucin glycoprotein-5AC   | MUC-5  |                  |
|  | Mucin glycoprotein-6   | MUC-6  |                  |
|  | Multiple myeloma oncogene-1  | MUM-1P   |                  |
|  | Myeloperoxidase in neutrophils and granulocytes  | MYELO  |                  |
|  | Rhabdomyosarcomas  | MYO-D1   |                  |
|  | Rhabdomyosarcoma and Wilm's tumours  | MYOGEN   |                  |
| FFPE Slides (formalin fixed paraffin embedded) tissue on glass slides,cell blocks and formalin fixed cytospin slides             | Pluripotent germ cell tumours, i.e. seminoma   | OCT 3/4  |                  |
| Silues   | Epithelial basal cell marker   | P63  |                  |
|  | HGPIN and prostatic adenocarcinoma   | P504S  |                  |

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| HUMAN BODY TISSUE<br>SAMPLES (cont'd)  | Histopathological examination activities for the purposes of clinical diagnosis  | In house documented procedures using manual methods or analysers in conjunction with manufacturer's instructions for the following methods (where relevant):  |                  |
| FFPE slides (Formalin fixed paraffin embedded) tissue on glass slides, cell blocks and formalins fixed cytospins slides (cont'd) | Immunohistochemistry to detect the following: (cont'd)  Prostatic glandular epithelium and prostate carcinoma  Thyroid, renal, Mullerian and thymic tumours  Activated T-cells and marker for angioimmunoblastic lymphoma  Expression of PD-L1 protein in NSCLC  Neuroendocrine cells and neurons  Cellular Progesterone receptor expression  Germ cell neoplasms and in breast, ovarian and lung carcinomas  Normal and neoplastic melanocytes, adipopcytes, neural cells and tumours | Immunocytochemistry Dako Omnis Basic User SOP: CP-IMM-SOP-33 Immunocytochemistry Dako Omnis Advanced User: CP-IMM-SOP-36 Immunocytochemistry Use of Dako Coverslipper: CP-IMM-SOP-18 Interpretive Microscopy procedures: Pathologist Reporting and Cut-up: CP-PATH-POL-2 and PD-L1 Reporting Procedures: CP-PATH-POL-6 PAPH  PAX-8  PD-1  PD-L1 PD-L1 PD-L1 PD-L1 PD-L1 PD-L7 PD-L1 |                  |

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| HUMAN BODY TISSUE<br>SAMPLES (cont'd)  | Histopathological examination activities for the purposes of clinical diagnosis (cont'd)                                    | In house documented procedures using manual methods or analysers in conjunction with manufacturer's instructions for the following methods (where relevant):  |                  |
| FFPE slides (Formalin fixed paraffin embedded) tissue on glass slides, cell blocks and formalins fixed cytospins slides (cont'd) | Immunohistochemistry to detect the following: (cont'd)  | Immunocytochemistry Dako Omnis Basic User SOP: CP-IMM-SOP-33  Immunocytochemistry Dako Omnis Advanced User: CP-IMM-SOP-36  Immunocytochemistry Use of Dako Coverslipper: CP-IMM-SOP-18  Interpretive Microscopy procedures: Pathologist Reporting and Cut-up: CP-PATH-POL-2 and PD-L1 Reporting Procedures: CP-PATH-POL-6 | A                |
|  | Smooth muscle, myoepithelial can other contractile cells  | SMA   |                  |
|  | Detection of primary and metastatic renal cell carcinomas   | RCC   |                  |
|  | Melanoma marker   | SOX-10  |                  |
|  | Neuroendocrine cells and neurones   | SYN   |                  |
|  | Marker for normal and malignant thyroid   | THGLOB  |                  |
|  | Dermal melanocytes, melanocytic lesions and malignant melanomas   | TYROS   |                  |
|  | Cells of mesenchymal origin and mesenchymal tuours  | VIM   |                  |
|  | Wilm's tumour, malignant mesothelioma, ovarian cystadenocarcinoma, nephroblastoma and desmoplastic small round cell tumours | WT-1  |                  |

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|--|--|--|------------------|
| HUMAN BODY TISSUE<br>SAMPLES (cont'd)  | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | In house documented procedures using manual methods or analysers in conjunction with manufacturer's instructions for the following methods (where relevant): | А                |
| FFPE slides (Formalin fixed paraffin embedded) tissue on glass slides, cell blocks and formalins fixed cytospins slides (cont'd) | Immunohistochemistry to detect the following: (cont'd)                                   | Immunocytochemistry Use of Dako<br>AS Link 48 SOP: CP-IMM-SOP-17<br>and Immunocytochemistry Use and<br>Operation of PT Link SOP: CP-<br>IMM-SOP-24           |                  |
| ,  |  | Immunocytochemistry Use of Dako<br>Coverslipper: CP-IMM-SOP-18   |                  |
|  |  | Interpretive Microscopy procedures: Pathologist Reporting and Cut-up: CP-PATH-POL-2 and PD-L1 Reporting Procedures: CP-PATH-POL-6                            |                  |
|  | Sebaceous carcinoma  | Adipophilin  |                  |
|  | Primary liver tumours and yolk sac tumours   | Alpha fetoprotein (AFP)<br>CP-IMM-COP-17   |                  |
|  | Myoglobin in skeletal and cardiac muscle   | MYOG   |                  |
|  | Anaplastic lymphoma kinase (CD246) in ALCL   | ALK-1  |                  |
|  | Hairy cell leukaemia   | Annexin A1   |                  |
|  | Dendritic cells  | CD11c  |                  |
|  | Common B-cell marker expressed on B-cells and follicular dendritic cells                 | CD19   |                  |
|  | Follicular dendritic cell  | CD21   |                  |
|  | IL-3 receptor in monocytes, neutrophils and basophils                                    | CD123  |                  |
|  | Macrophages  | CD163  |                  |
|  | Endogenous C-Myc   | C-MYC  |                  |

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| HUMAN BODY TISSUE<br>SAMPLES (cont'd)  | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | In house documented procedures using manual methods or analysers in conjunction with manufacturer's instructions for the following methods (where relevant): |                  |
| FFPE slides (Formalin fixed paraffin embedded) tissue on glass slides, cell blocks and formalins fixed cytospins slides (cont'd) | Immunohistochemistry to detect the following: (cont'd)                                   | Immunocytochemistry Use of Dako<br>AS Link 48 SOP: CP-IMM-SOP-17<br>and Immunocytochemistry Use and<br>Operation of PT Link SOP: CP-<br>IMM-SOP-24           | А                |
|  |  | Immunocytochemistry Use of Dako Coverslipper: CP-IMM-SOP-18  |                  |
|  |  | Interpretive Microscopy procedures: Pathologist Reporting and Cut-up: CP-PATH-POL-2 and PD-L1 Reporting Procedures: CP-PATH-POL-6                            |                  |
|  | B-cell centroblastic cell line   | DBA44  |                  |
|  | Epstein Barr Virus infection   | EBV  |                  |
|  | Erythroid cells  | GLYCA (Glycophorin A)  |                  |
|  | Splenic marginal zone lymphoma and B-cell lymphocytic lymphoma                           | IgD delta chain  |                  |
|  | Mast cells   | MCT  |                  |
|  | Neuronal marker  | NFP (Neurofilamnet protein)  |                  |
|  | Marker of molar pregnancy  | P57  |                  |
|  | Renal cell oncocytoma tumour   | RON-A  |                  |
|  | Detection of SV40 virus in renal transplant samples                                      | SV40   |                  |
|  | Thymic cortical lymphocytes and lymphoblastic lymphomas and leukaemias                   | TDT  |                  |
| FFPE slides (formalin fixed paraffin embedded) tissue  | Cytotoxic T-cells  | TIA-1  |                  |
| on glass slides  |  | OCT 2  |                  |

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|--|--|--|------------------|
| HUMAN BODY TISSUE<br>SAMPLES (cont'd)  | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | In house documented procedures using manual methods or analysers in conjunction with manufacturer's instructions for the following methods (where relevant): | А                |
| FFPE slides<br>(Formalin fixed paraffin<br>embedded) tissue on glass<br>slides and cell blocks | Immunohistochemistry to detect the following: (cont'd)                                   | Ventana Bench Mark Ultra<br>CP-IMM-SOP-19  |                  |
|  | ALK protein in NSCLC   | ALKD5F3  |                  |
|  | HER2 amplification in breast tumours   | HER-2  |                  |
|  | Expression of PD-L1 protein in NSCLC   | PD-L1  |                  |
|  | Dermatofibroma   | FAC 13A  |                  |
|  |  | GATA-3   |                  |
|  |  | NKX3.1   |                  |
|  |  | ROS1 (clone SP384)   |                  |
|  | Mantle cell lymphoma   | BCL-1 (Cyclin -D1)   |                  |
|  | Marker of rejection in renal transplants   | CD4  |                  |
|  | Glial fibrillary acidic protein neural cells   | GFAP (Glian fibrillary acidic protein)   |                  |
|  | Smooth muscle and myoepithelial cells  | SMMS-1   |                  |
|  | Mantle cell lymphoma marker  | SOX-11   |                  |
| FFPE Slides (formalin fixed  |  | PD-L1 (clone SP142)  |                  |
| paraffin embedded) tissue on glass slides  |  | STAT6  |                  |
|  |  |  |                  |
|  |  |  |                  |

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|---------------------------------------|--|--|------------------|
| HUMAN BODY TISSUE<br>SAMPLES (cont'd) | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | In house documented procedures using manual methods or analysers in conjunction with manufacturer's instructions for the following methods (where relevant): | А                |
| Fresh frozen skin biopsy tissue       | Identification of: Immunoglobulins and complement  | Direct Immunofluorescence technique:   |                  |
|                                       |  | Documented in-house procedures in conjunction with manufacturer's instructions using DAKO FITC-conjugated antibodies   |                  |
|                                       |  | Manual techiques<br>CP-IMM-SOP-16  |                  |
|                                       |  | IgA  |                  |
|                                       |  | IgG  |                  |
|                                       |  | C3   |                  |
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|--|--|--|------------------|
| HUMAN BODY TISSUE<br>SAMPLES (cont'd)                                | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | In house documented procedures using manual methods or analysers in conjunction with manufacturer's instructions for the following | А                |
|  | Molecular Pathology  | methods (where relevant):  |                  |
|  | Morphological assessment and interpretation/diagnosis                                    |  |                  |
| Stained slides prepared as above                                     | Fluorescent in-situ hybridisation (FISH)   |  |                  |
| Breast tissue  | Determination of HER 2 gene amplification  | Automated techniques using Dako<br>Omnis<br>CP-MOL-SOP-17  |                  |
|  |  | Fluorescence microscope Olympus<br>BX 61<br>CP-MOL-SOP-15  |                  |
|  |  | Interpretive/diagnostic microscopy<br>CP-IMM-SOP-11  |                  |
|  |  | Evaluation and reporting of HER 2 tests CP-IMM-SOP-11  |                  |
| FFPE tissue, cell blocks, cytospin slides                            |  | ROS 1IQFISH Break-apart probe  |                  |
| FFPE slides<br>(Formalin fixed paraffin<br>embedded) tissue on glass | Chromogenic in situ hybridisation (CISH)   |  |                  |
| slides   |  | Automated techniques using<br>Ventana Benchmark Ultra<br>CP-IMM-SOP-19 and CISH probes   |                  |
|  | Epstein Barr Virus RNA   | INFORM EBER probe  |                  |
|  |  |  |                  |
|  |  |  |                  |

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|---|--|--|------------------|
| HUMAN BODY TISSUE<br>SAMPLES (cont'd)                                 | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | In house documented procedures using manual methods or analysers in conjunction with manufacturer's instructions for the following | А                |
|   | Molecular Pathology (cont'd)   | methods (where relevant):  |                  |
|   | Morphological assessment and interpretation/diagnosis (cont'd)                           |  |                  |
| Tissue block  | BRAF mutation screening  | Automated techniques using Biocartis Idylla CP-MOL-SOP-25  |                  |
|   | EGFR mutation screening  | CF-MOL-SOF-25  |                  |
| FFPE samples, vitrous fluid, whole blood                              | DNA extraction   | Automated technique using QIAcube CP-MOL-SOP-23  |                  |
| Genomic DNA from the above sample types                               | DNA quantification   | Automated technique using Quibit<br>4.0 Fluorimeter and Quibit dsDNA<br>BR assay kit<br>CP-MOL-SOP-24                              |                  |
| Genomic DNA from the above sample types                               | Detection of B and T cell gene mutation  | Clonality Assay using ABI 3500<br>CP-MOL-SOP-20<br>CP-MOL-SOP-19   |                  |
| Genomic DNA extracted and quantified from FFPE using above techniques | Non-Small Cell Lung Cancer (NSCLC)   | Next Generation Sequencing using Genexus Integrated Sequencer and Oncomine Precision Assay GX                                      |                  |
|   |  | Data analysis using Oncomine<br>Precision GX Solid Tumour DNA<br>and Fusions workflow<br>CP-MOL-SOP-32                             |                  |
|   | END  | 1  | 1                |

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