


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

|   |   |   |
|---|---|---|
| <br><b>8726</b><br>Accredited to<br>ISO 15189:2022 | <b>Trustees of The London Clinic Ltd</b>  |   |
|   | <b>Issue No: 007    Issue date: 03 March 2025</b>   |   |
|   | <b>Department of Cellular Pathology</b><br><b>The London Clinic</b><br>116 Harley Street<br>London<br>W1G 7JL | <b>Contact: Beverley Barker (Quality Manager)</b><br><b>Tel: +44 (0) 020 7616 7755</b><br><b>Fax: +44 (0) 020 7616 7687</b><br><b>E-Mail: B.Barker@thelondonclinic.co.uk</b><br><b>Website: www.thelondonclinic.co.uk</b> |
| Testing performed by the Organisation at the locations specified below  |   |   |

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

#### Laboratory locations:

| Location details: Department of Cellular Pathology                            |   | Activity  | Location code |
|---|---|---|---------------|
| <b>Address</b><br>The London Clinic<br>116 Harley Street<br>London<br>W1G 7JL | <b>Local contact</b><br>Beverley Barker | Histology<br>Non-gynae Cytology<br>Gynae cytology: preparation of unstained slides for subsequent staining/reporting by accredited laboratory | A             |

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

| Location details              |                 | Activity  | Location code |
|-------------------------------|-----------------|---|---------------|
| 20 Devonshire Place<br>London | Beverley Barker | Preparation and staining of tissue for interpretation by the pathologist in Mohs Clinic | B             |



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**DETAIL OF ACCREDITATION**

| Materials/Products tested   | Type of test/Properties measured/Range of measurement   | Standard specifications/ Equipment/Techniques used  | Location Code                         |
|---|---|---|---------------------------------------|
| <b>HUMAN BODY TISSUE</b>  | <u>Histopathological examination activities for the purposes of clinical diagnosis</u>  | In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:  |                                       |
| Fixed, paraffin-wax processed tissue (diagnostic / biopsy, excision and resection specimens) of human origin excluding advanced infiltration of fatty tissues | Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis | In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:<br><br>Specimen Dissection including decalcification where necessary<br><br>HTSOP16<br>HTSOP30<br>HTSOP7<br><br>Tissue processing using Leica VIP6AI , Sakura Tissue Tek VIP6 and VIP6AI<br>HTSOP55<br><br>Tissue embedding<br>Sakura Tissue Tek 5 and Tissue Tek 6<br>HTSOP27<br><br>Microtomy<br>Leica (Biocut, RM2135, RM2235and Thermo Finesse Microtomes<br>HTSOP28<br><br>Exakt Bone Saw for decalcified specimens HTSOP57 | A<br><br>A<br><br>A<br><br>A<br><br>A |
| Fresh (unfixed and unprocessed) tissue of human origin  | Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis | Frozen Section using ThermoScientific NX50 cryostat<br><br>Manual H&E staining<br><br>HTSOP4  | A                                     |



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| HUMAN BODY TISSUE (cont'd)                     | <u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u> | In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified               |               |
| FFPE slides (Formalin fixed paraffin embedded) | Demonstration of :  | Manual techniques unless otherwise specified  |               |
|  | Basophilic and eosinophilic structures  | Automated Haematoxylin and Eosin using Sakura Prisma Plus autostainer HTSOP20   | A             |
|  | Weakly sulphated and acidic mucins  | Alcian Blue (AB) technique HTSSOP2  | A             |
|  | Acidic and neutral mucins   | Alcian Blue Periodic Acid-Schiff (AB PAS) technique Manual and Automated on the Sakura Prisma Plus autostainer Add with +/-diastase HTSSOP3 | A             |
|  | Amyloid   | Congo Red technique HTSSOP4   | A             |
|  | <i>Helicobacter pylori</i> -like organisms  | Cresyl Fast Violet (CFV) technique Manual and/or Automated on the Sakura Prisma Plus autostainer HTSSOP5                                    | A             |
|  | Elastic connective tissue fibres  | Elastic van-Gieson (EVG) (Miller's) technique HTSSOP6   | A             |
|  | Haematopoietic cells and <i>Helicobacter pylori</i> -like organisms                             | Giemsa HTSSOP27   | A             |
|  | Reticulin connective tissue fibres  | Gordon and Sweet's silver technique HTSSOP08  | A             |
|  | Gram positive and negative bacteria   | Gram technique HTSSOP9  | A             |



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| HUMAN BODY TISSUE (cont'd)                              | <u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u> | In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified |               |
| FFPE slides (Formalin fixed paraffin embedded) (cont'd) | Demonstration of : (cont'd)   | Manual techniques unless otherwise specified  |               |
|   | Fungi   | Grocott technique<br>HTSSOP11   | A             |
|   | Mast cells  | Giemsa HTSSOP29<br>Toluidine Blue Manual and/or Automated on the Sakura Prisma Plus autostainer<br>HTSSOP31                   | A             |
|   | Iron / haemosiderin   | Perls Prussian Blue technique<br>HTSSOP21   | A             |
|   | Fibrin  | Martius Yellow Brilliant Crystal Scarlet Soluble Blue (MSB) technique<br>HTSSOP17   | A             |
|   | Melanin   | Masson Fontana silver technique<br>HTSSOP13   | A             |
|   | Connective tissue elements  | Masson Trichrome technique<br>HTSSOP14  | A             |
|   | Presence/absence of melanin   | Melanin bleach<br>HTSSOP15  | A             |
|   | Hepatitis B surface antigen, copper-associated protein and elastic connective tissue fibres     | Orcein (Shikata) technique<br>HTSSOP19  | A             |
|   | Presence/absence of glycogen  | Diastase Periodic Acid-Schiff (D PAS/PAS) technique Manual and/or automated on the Sakura Prisma Plus autostainer<br>HTSSOP20 | A             |
|   | Collagen connective tissue fibres   | van-Gieson technique<br>HTSSOP12  | A             |



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| HUMAN BODY TISSUE (cont'd)                              | <u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u> | In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified          |               |
| FFPE slides (Formalin fixed paraffin embedded) (cont'd) | Demonstration of : (cont'd)   | Manual techniques unless otherwise specified   |               |
|   | Mycobacteria  | Wade fite HTSSSOP30  | A             |
|   | Spirochetes   | Warthin Starry silver technique HTSSOP26   | A             |
|   | Detection of acid and alcohol-fast bacilli  | Ziehl-Neelsen (ZN) technique HTSSOP1   | A             |
|   | <u>Immunohistochemistry to detect the following:</u>  | Documented in-house methods used in accordance with manufacturer's operating instructions for the use of Roche Benchmark Ventana Ultra |               |
|   |   | HIMMSOP5   |               |
| FFPE slides (Formalin fixed paraffin embedded)          | Multicytokeratin  | AE1 / 3  | A             |
|   | Diffuse lymph proliferative disease and neoplastic cells of follicular lymphoma                 | Bcl-2  | A             |
|   | Myoepithelial cells   | Calponin   | A             |
|   | Mesothelioma  | Calretinin   | A             |
|   | Cytokeratin   | Cam 5.2  | A             |
|   | T cells   | CD3  | A             |
|   | B cells   | CD20   | A             |
|   | Reed Sternberg cells, plasma cells  | CD30   | A             |
|   | Haematopoietic cells, vascular endothelium  | CD34   | A             |



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| HUMAN BODY TISSUE (cont'd) | <u>Immunohistochemistry to detect the following:</u> (cont'd)                       | Documented in-house methods used in accordance with manufacturer's operating instructions for the use of Roche Benchmark Ventana Ultra (cont'd) |               |
| FFPE slides (cont'd)       | LCA for pan lymphocyte  | CD45  | A             |
|                            | Natural Killer cells , neuroendocrine tissue, macrophages, monocytes, myeloid cells | CD56  | A             |
|                            | CEA glycoproteins   | CEA (Carcino Embryonic Antigen)   | A             |
|                            | Mast cells B cells Plasma cells   | CD79a   | A             |
|                            | Tissues of neuroendocrine origin  | Chromogranin A  | A             |
|                            | Cytomegalovirus   | Cytomegalovirus (CMV)   | A             |
|                            | Stratified squamous epithelium, basal cells, mesotheliomas                          | Cytokeratin 5/6 (CK5/6)   | A             |
|                            | Normal and neoplastic epithelia   | Cytokeratin 7(CK7)  | A             |
|                            | Adenocarcinomas, columnar epithelial cells  | Cytokeratin 20 (CK20)   | A             |
|                            | Striated and smooth muscle  | Desmin  | A             |
|                            | Normal duct epithelium, ductal carcinoma  | E-Cadherin  | A             |
|                            | Normal and neoplastic epithelium  | Epithelial Membrane Antigen   | A             |
|                            | Glial fibrillary acidic protein   | GFAP  | A             |
|                            | Melanosomes   | HMB45   | A             |
|                            | Proliferating cells   | Ki67  | A             |
|                            | Melanoma marker   | Melan-A   | A             |



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| HUMAN BODY TISSUE (cont'd) | <u>Immunohistochemistry to detect the following:</u> (cont'd)       | Documented in-house methods used in accordance with manufacturer's operating instructions for the use of Roche Benchmark Ventana Ultra (cont'd) |               |
| FFPE slides (cont'd)       | Broad range cytokeratins  | MNF116  | A             |
|                            | Germ cell tumours   | PLAP  | A             |
|                            | Prostate secretory and ductal epithelium                            | Prostate Specific Antigen   | A             |
|                            | Burkitt Lymphoma, follicular lymphoma, Pre-cursor B cell lymphoma   | CD10  | A             |
|                            | GI Adenocarcinoma and Carcinoids                                    | CDX2  | A             |
|                            | GIST tumours, mast cell disease                                     | CD117   | A             |
|                            | Stratified epithelial cells, epidermal cells, basal cells           | CK14  | A             |
|                            | Breast, urothelial, skin neoplasms                                  | GATA-3  | A             |
|                            | H. Pylori organisms   | H Pylori  | A             |
|                            | Mismatch repair protein differential diagnosis of colorectal cancer | MLH1  | A             |
|                            | Mismatch repair protein differential diagnosis of colorectal cancer | MSH2  | A             |
|                            | Mismatch repair protein differential diagnosis of colorectal cancer | MSH6  | A             |
|                            | Seminomas   | Oct4  | A             |
|                            | Epithelial neoplasms  | PAX-8   | A             |



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| HUMAN BODY TISSUE (cont'd)        | <u>Immunohistochemistry to detect the following:</u> (cont'd)             | Documented in-house methods used in accordance with manufacturer's operating instructions for the use of Roche Benchmark Ventana Ultra (cont'd) |               |
| FFPE slides (cont'd)              | HPV anogenital lesions  | P16   | A             |
|                                   | Mismatch repair protein differential diagnosis of colorectal cancer       | PMS2  | A             |
|                                   | Mutational analysis for carcinomas  | P53   | A             |
|                                   | Prostate cancer cells   | PSMA  | A             |
|                                   | Schwann cells, nerve processes, S100+ neoplasms                           | S100  | A             |
|                                   | Prostate acid phosphatase   | PSAP  | A             |
|                                   | Smooth muscle cells, myoepithelium  | Smooth Muscle Actin   | A             |
|                                   | Neuroendocrine cells  | Synaptophysin   | A             |
|                                   | Thyroid follicular cells  | TTF-1   | A             |
|                                   | Cells of mesenchymal origin   | Vimentin  | A             |
|                                   | Epithelial cells and smooth muscle of fallopian tube origin. Wilms tumour | WT-1  | A             |
| Slides prepared in house as above | Morphological assessment and interpretation/diagnosis                     | HNTASOP21   | A             |





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| <p>HUMAN BODY TISSUE (cont'd)</p> <p>Skin samples for Moh's micrographic surgery</p>  | <p><u>Histopathological examination activities for the purposes of clinical diagnosis</u></p> <p>Rapid diagnosis of basal cell carcinoma</p>  | <p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified</p> <p>Preparation of tissue samples, microtomy, staining and review for adequacy</p> <p>Leica Cryostat CM1850UV<br/>Toluidine Blue manual staining technique</p> <p>HTSOP52<br/>HTSSOP28</p>  | B                 |
| <p>HUMAN BODY TISSUE/CELLS</p> <p>Bronchial brushings, Body fluids, Cerebrospinal Fluid (CSF), Fine Needle Aspirates, Gastro-Intestinal (GI) and biliary brushings, Joint fluids, Serous Effusions, Urine, Needle Washings</p> <p>Slides prepared in house as above</p> | <p><u>Cytopathological (Non-Gynae) examination activities for the purposes of clinical diagnosis</u></p> <p>Examination of cellular material in order to identify or exclude morphological and cytological abnormalities</p> <p>Morphological assessment and interpretation/diagnosis</p> | <p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>ThinPrep Liquid-Based Cytology (LBC) automated sample preparation and staining using Hologic T2000 manual and/or automated Sakura Prisma Plus autostainer Papanicalou staining May Grunwald Giemsa staining (manual)<br/>CSOP30<br/>CSOP10<br/>HTSOP20</p> <p>HNTSOP30</p> | <p>A</p> <p>A</p> |
| END   |   |   |                   |