


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

|                                                                                                                                                        |                                                                                            |                                                                                                                                                                          |
|--------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <br><b>UKAS</b><br>MEDICAL<br>8130<br>Accredited to<br>ISO 15189:2012 | <b>North Bristol NHS Trust</b>                                                             |                                                                                                                                                                          |
|                                                                                                                                                        | Issue No: 002    Issue date: 26 June 2019                                                  |                                                                                                                                                                          |
|                                                                                                                                                        | <b>Cellular Pathology</b><br>Southmead Hospital<br>Westbury on Trym<br>Bristol<br>BS10 5NB | <b>Contact: Mr Andrew Heryet</b><br>Tel: +44 (0) 1173 232706<br>Fax: +44 (0) 1173 238476<br>E-Mail: andrew.heryet@nbt.nhs.uk<br>Website: www.nbt.nhs.uk/severn-pathology |
| Testing performed by the Organization at the locations specified below                                                                                 |                                                                                            |                                                                                                                                                                          |

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

#### Laboratory locations:

| Location details                                                                                      |                                                                                                                                      | Activity                                                                                                                                                                                      | Location code |
|-------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| <b>Address</b><br>Cellular Pathology<br>Southmead Hospital<br>Westbury on Trym<br>Bristol<br>BS10 5NB | <b>Local contact</b><br>Mr Andrew Heryet<br>Tel: +44 (0) 1173 232706<br>Fax: +44 (0) 1173 238476<br>E-Mail: Andrew.heryet@nbt.nhs.uk | Histopathology<br>Diagnostic Cytopathology<br>Gynaecological Cytopathology<br>Rapid frozen section for intra-operative diagnosis<br>FNA material/slide preparation and cellularity assessment | A             |



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

| Location details                                                                                                                                                                                                                                                        | Activity                                                                                                                                                                                             | Location code |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| <p><b>Address</b><br/>Brunel Building<br/>Southmead Hospital<br/>Westbury on Trym<br/>Bristol<br/>BS10 5NB</p> <p><b>Local contact</b><br/>Mr Andrew Heryet<br/>Tel: +44 (0) 1173 232706<br/>Fax: +44 (0) 1173 238476<br/>E-Mail: Andrew.heryet@nbt.nhs.uk</p>          | <p>One Stop Nucleic Acid assays OSNA</p>                                                                                                                                                             | <p>B</p>      |
| <p><b>Address</b><br/>Cellular Pathology<br/>Bristol Royal Infirmary<br/>Marlborough Street<br/>Bristol<br/>BS2 8HW</p> <p><b>Local contact</b><br/>Mr Andrew Heryet<br/>Tel: +44 (0) 1173 232706<br/>Fax: +44 (0) 1173 238476<br/>E-Mail: Andrew.heryet@nbt.nhs.uk</p> | <p>Dissection and preparation and reporting of biopsies<br/>Diagnostic cytology, screening and reporting of urgent Head and Neck biopsies<br/>Rapid frozen section for intra-operative diagnosis</p> | <p>C</p>      |
| <p><b>Address</b><br/>Mortuary<br/>Southmead Hospital<br/>Westbury on Trym<br/>Bristol<br/>BS10 5NB</p> <p><b>Local contact</b><br/>Mr Andrew Heryet<br/>Tel: +44 (0) 1173 232706<br/>Fax: +44 (0) 1173 238476<br/>E-Mail: Andrew.heryet@nbt.nhs.uk</p>                 | <p>Storage of bodies</p>                                                                                                                                                                             |               |
| <p><b>Address</b><br/>Perinatal Mortuary<br/>St Michaels Hospital<br/>Southwell Street<br/>Bristol<br/>BS2 8EG</p> <p><b>Local contact</b><br/>Mr Andrew Heryet<br/>Tel: +44 (0) 1173 232706<br/>Fax: +44 (0) 1173 238476<br/>E-Mail: Andrew.heryet@nbt.nhs.uk</p>      | <p>Storage of bodies</p>                                                                                                                                                                             |               |





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| HUMAN TISSUES AND FLUIDS (cont'd)               | <u>Histopathology</u> (cont'd)<br>Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd) | Macroscopic and microscopic examination using documented in-house procedures in conjunction with manufacturer's instructions (where relevant)<br><br><u>Embedding</u><br>Manual method using Leica EG115H/E1150C, EG1160 and Histocare Arcadia embedding centres and in-house procedure: CP-HiML-SOP-19<br><br><u>Microtomy</u><br>Automated method using Leica RM2135/2235/2245/2255 microtomes and in-house procedure: CP-HiML-SOP-20 | A             |
| Formalin fixed, paraffin embedded (FFPE) tissue | Routine morphological staining                                                                                                            | <u>Routine Haematoxylin and Eosin staining</u> and coverslipping using: Leica Autostainer CV5030 and XL ST5020/CV5030 stainer / cover slippers and in-house procedure: CP-HiML-SOP-21<br>CP-HiML-SOP-22                                                                                                                                                                                                                                 | A             |
| Fresh Tissue<br>Frozen Tissue                   | Intra-operative diagnosis                                                                                                                 | <u>Rapid Frozen Section</u><br>Leica CM1950<br>Leica CM1850 UV<br>using and manual Haematoxylin and Eosin (H and E) stain with in-house procedure:<br>CP-HiCU-SOP-19<br>CP-HiCU-SOP-12                                                                                                                                                                                                                                                  | A<br>C        |
|                                                 | Identification of Hirschsprungs disease                                                                                                   | Manual Acetyl Cholinesterase (ACHE) stain with in-house procedure:<br>CP-HiSD-SOP-37                                                                                                                                                                                                                                                                                                                                                    | A             |



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|------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| HUMAN TISSUES AND FLUIDS (cont'd)<br><br>Formalin fixed, paraffin embedded (FFPE) tissue | <u>Histopathology</u> (cont'd)<br><br>Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd)<br><br>Detection of:<br><br>Acid and neutral mucins<br><br>Amyloid<br><br>Copper deposits<br><br>Haematopoietic cells<br><br>H. pylori<br><br>Reticulin fibres<br><br>Gram positive and negative bacteria<br><br>Basement membrane, Fungi<br><br>General morphology nuclei, cytoplasm & connective tissue<br><br>General morphology nuclei, cytoplasm & connective tissue<br><br>Connective tissue collagen | Macroscopic and microscopic examination using documented in-house procedures in conjunction with manufacturer's instructions (where relevant)<br><br><u>Special Staining</u><br>Manual Techniques using in-house procedures and the following stains:<br><br>Alcian blue-PAS<br>CP-HiSD-SOP-ABPASD<br><br>Congo red<br>CP-HiSD-SOP-CR<br><br>Dimethylaminobenzylidene<br>Rhodanine DMABR<br>CP-HiSD-SOP-DMABR<br><br>Giemsa<br>CP-HiSD-SOP-Giemsa<br><br>Giemsa modified<br>CP-HiSD-SOP-ModifiedGiemsa<br><br>Gordon and Sweets reticulin stain<br>CP-HiSD-SOP-Retic<br><br>Gram<br>CP-HiSD-SOP-Gram<br><br>Grocott methenamine silver<br>CP-HiSD-SOP-Grocott<br><br>Haematoxylin and eosin manual<br>CP-HiSD-SOP-Manual<br><br>Haematoxylin and eosin rapid<br>CP-HiSD-SOP-Rapid<br><br>Haematoxylin Van Gieson HVG<br>CP-HiSD-SOP-HVG | A             |



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| FFPE Tissue (cont'd)              | Detection of: (cont'd)                                                                                                                    | <u>Special Staining</u> Manual (cont'd)                                                                                                       |               |
|                                   | Fibrin & connective tissue                                                                                                                | Martius scarlet blue MSB<br>CP-HiSD-SOP-MSB                                                                                                   |               |
|                                   | Melanin                                                                                                                                   | Masson Fontana<br>CP-HiSD-SOP-MassonFontana                                                                                                   |               |
|                                   | Connective tissue                                                                                                                         | Masson Trichrome<br>CP-HiSD-SOP-MBT                                                                                                           |               |
|                                   | Removal of melanin pigment                                                                                                                | Melanin Bleach<br>CP-HiSD-SOP-MelaninBleach                                                                                                   |               |
|                                   | Elastic fibres & connective tissue                                                                                                        | Miller's elastic Van Gieson EVG<br>CP-HiSD-SOP-EVG                                                                                            |               |
|                                   | Neutral mucins                                                                                                                            | Oil red O<br>CP-HiSD-SOP-OilRedO                                                                                                              |               |
|                                   | Hepatitis B surface antigen and copper associated protein                                                                                 | Orcein (Shikata)<br>CP-HiSD-SOP-Orcein                                                                                                        |               |
|                                   | Polysaccharides including glycogen                                                                                                        | Periodic acid Schiff PAS<br>CP-HiSD-SOP-PAS                                                                                                   |               |
|                                   | Basement membrane                                                                                                                         | Periodic acid silver PAAG<br>CP-HiSD-SOP-PAAG                                                                                                 |               |
|                                   | Haemosiderin                                                                                                                              | Perl's Prussian blue<br>CP-HiSD-SOP-Perls                                                                                                     |               |
|                                   | Lipofuscin, melanin and argentaffin granules                                                                                              | Schmorls<br>CP-SHIS-SOP-004 (no24)                                                                                                            |               |
|                                   | Amyloid                                                                                                                                   | Sirius red<br>CP-SHIS-SOP-004 (no25)                                                                                                          |               |
|                                   | Mast cells                                                                                                                                | Toluidine blue<br>CP-SHIS-SOP-004 (no26)                                                                                                      |               |



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| FFPE Tissue (cont'd)              | Detection of: (cont'd)                                                                                                                    | <u>Special Staining Manual (cont'd):</u>                                                                                                        |               |
|                                   | Fungi                                                                                                                                     | Tome for fungi<br>CP-SHIS-SOP-004 (no27)                                                                                                        |               |
|                                   | Calcium salts                                                                                                                             | Von Kossa<br>CP-SHIS-SOP-004 (no 28)                                                                                                            |               |
|                                   | Acid fast bacilli e.g. Mycobacterium leprae                                                                                               | Wade Fite<br>CP-SHIS-SOP-004 (no29)                                                                                                             |               |
|                                   | Acid fast bacilli e.g. Mycobacterium tuberculosis                                                                                         | Ziehl-Neelsen ZN<br>CP-HiSD-SOP-ZN                                                                                                              |               |
| FFPE Tissue                       | Detection of the following:                                                                                                               | <u>Immunohistochemistry</u><br>Automated methods using Bond III IHC instruments using in-house procedures:<br>CP-HiSD-SOP-ICC<br>CP-HiSD-SOP-36 |               |
|                                   | High MW Cytokeratin                                                                                                                       | 34BE12                                                                                                                                          |               |
|                                   | Pan-cytokeratin CK1-8, 10, 14-16 and 19                                                                                                   | AE1/3                                                                                                                                           |               |
|                                   | Adenovirus                                                                                                                                | Adenovirus                                                                                                                                      |               |
|                                   | Carcinoma marker liver, kidney, colon & prostate                                                                                          | AMACR P504s                                                                                                                                     |               |
|                                   | Carcinoma marker prostate                                                                                                                 | AMACR/34BE12                                                                                                                                    |               |
|                                   | Amyloid                                                                                                                                   | Amyloid A component                                                                                                                             |               |
|                                   | Germ Cell Tumours                                                                                                                         | Alpha Feto Protein (AFP)                                                                                                                        |               |



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| FFPE Tissue (cont'd)              | Detection of the following: (cont'd)                                                                                                      | <u>Immunohistochemistry</u><br>Automated methods using Bond III IHC instruments using in-house procedures:<br>CP-HiSD-SOP-ICC<br>CP-HiSD-SOP-36 |               |
|                                   | Human p80 protein                                                                                                                         | ALK-1 (Lymphoma)                                                                                                                                |               |
|                                   | Tumour Suppressor Gene                                                                                                                    | BAF47                                                                                                                                           |               |
|                                   | T-cells, B-cells in the mantle zone                                                                                                       | bcl-2                                                                                                                                           |               |
|                                   | Follicular centre B-cells                                                                                                                 | bcl-6                                                                                                                                           |               |
|                                   | B cells, plasma cells follicular lymphomas and lymphomas                                                                                  | BOB -1                                                                                                                                          |               |
|                                   | Marker in renal glomerulopathy                                                                                                            | C1q (renal)                                                                                                                                     |               |
|                                   | Marker in renal glomerulopathy                                                                                                            | C3c (renal)                                                                                                                                     |               |
|                                   | Marker in renal glomerulopathy                                                                                                            | C4d (renal)                                                                                                                                     |               |
|                                   | Ovarian epithelial malignancies, seminal vesicle carcinoma, anaplastic lymphoma                                                           | Ca 125                                                                                                                                          |               |
|                                   | Medullary Thyroid Tumours                                                                                                                 | Calcitonin                                                                                                                                      |               |
|                                   | Mesothelial cell lining                                                                                                                   | Calretinin                                                                                                                                      |               |





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| FFPE Tissue (cont'd)              | Detection of the following: (cont'd)                                                                                                      | <u>Immunohistochemistry</u><br>Automated methods (cont'd)<br>Bond III IHC instruments and in-house procedures:<br>CP-HiSD-SOP-ICC<br>CP-HiSD-SOP-36 |               |
|                                   | Epithelial cells, low molecular weight                                                                                                    | CAM5.2                                                                                                                                              |               |
|                                   | T-cell marker                                                                                                                             | CD2                                                                                                                                                 |               |
|                                   | T-cell marker                                                                                                                             | CD3                                                                                                                                                 |               |
|                                   | T-helper cells                                                                                                                            | CD4                                                                                                                                                 |               |
|                                   | T-cells, B-cells in the mantle zone                                                                                                       | CD5                                                                                                                                                 |               |
|                                   | Cytotoxic T-cells                                                                                                                         | CD8                                                                                                                                                 |               |
|                                   | Mature B cells, follicular dendritic cells, CALLA                                                                                         | CD10                                                                                                                                                |               |
|                                   | Dendritic cells                                                                                                                           | CD11c                                                                                                                                               |               |
|                                   | Immature B lymphocytes                                                                                                                    | CD15                                                                                                                                                |               |
|                                   | B-cell marker                                                                                                                             | CD20                                                                                                                                                |               |
|                                   | Mature B-cells and FDC                                                                                                                    | CD21                                                                                                                                                |               |
|                                   | FDC and EBV transformed blasts                                                                                                            | CD23                                                                                                                                                |               |
|                                   | Inflammatory and malignant conditions                                                                                                     | CD25                                                                                                                                                |               |
|                                   | RS cells                                                                                                                                  | CD30                                                                                                                                                |               |



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| FFPE Tissue (cont'd)              | Detection of the following: (cont'd)                                                                                                      | <u>Immunohistochemistry</u><br>Automated methods (cont'd)<br>Bond III IHC instruments and in-house procedures:<br>CP-HiSD-SOP-ICC<br>CP-HiSD-SOP-36 |               |
|                                   | Endothelial Cell Marker                                                                                                                   | CD31                                                                                                                                                |               |
|                                   | Endothelial marker                                                                                                                        | CD34                                                                                                                                                |               |
|                                   | T-cell and myeloid cells                                                                                                                  | CD43 (MT1)                                                                                                                                          |               |
|                                   | Leukocyte common antigen                                                                                                                  | CD45 (LCA)                                                                                                                                          |               |
|                                   | Neutral cell adhesion molecule                                                                                                            | CD56                                                                                                                                                |               |
|                                   | Platelet glycoprotein IIIa                                                                                                                | CD61                                                                                                                                                |               |
|                                   | Macrophages                                                                                                                               | CD68 (KP1)                                                                                                                                          |               |
|                                   | Monocytes & Macrophages                                                                                                                   | CD68 (PG-M1)                                                                                                                                        |               |
|                                   | Mast cells and GIST                                                                                                                       | CD117                                                                                                                                               |               |
|                                   | Plasma cells                                                                                                                              | CD138                                                                                                                                               |               |
|                                   | B-cell marker                                                                                                                             | CD79a                                                                                                                                               |               |
|                                   | Ewings sarcoma, T cell Lymphoma                                                                                                           | CD99                                                                                                                                                |               |
|                                   | Intestinal epithelial cells, colorectal + other adenocarcinomas                                                                           | CDX2                                                                                                                                                |               |
|                                   | Carcinoembryonic antigen                                                                                                                  | CEA                                                                                                                                                 |               |
|                                   | Neuroendocrine                                                                                                                            | Chromogranin A                                                                                                                                      |               |



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| FFPE Tissue (cont'd)              | Detection of the following: (cont'd)                                                                                                      | <u>Immunohistochemistry</u><br>Automated methods (cont'd)<br>Bond III IHC instruments and in-house procedures:<br>CP-HiSD-SOP-ICC<br>CP-HiSD-SOP-36 |               |
|                                   | Gastrointestinal epithelia                                                                                                                | CK20                                                                                                                                                |               |
|                                   | Squamous and myoepithelial cells                                                                                                          | CK5/6                                                                                                                                               |               |
|                                   | Normal and neoplastic epithelia                                                                                                           | CK7                                                                                                                                                 |               |
|                                   | Stratified epithelial cells                                                                                                               | CK14                                                                                                                                                |               |
|                                   | Epithelial cells, low molecular weight                                                                                                    | CK8/18                                                                                                                                              |               |
|                                   | Cytomegalovirus infected cells                                                                                                            | CMV                                                                                                                                                 |               |
|                                   | Aggressive B cell lymphoma likely to harbour a c Myc rearrangement                                                                        | C-Myc                                                                                                                                               |               |
|                                   | Mantle cell lymphoma                                                                                                                      | Cyclin D1                                                                                                                                           |               |
|                                   | Classification of lymphatic invasion of primary tumours                                                                                   | D2-40                                                                                                                                               |               |
|                                   | Striated and smooth muscle cells                                                                                                          | Desmin                                                                                                                                              |               |
|                                   | Epstein Barr virus infected cells                                                                                                         | EBV                                                                                                                                                 |               |
|                                   | Normal and neoplastic epithelium                                                                                                          | EMA                                                                                                                                                 |               |



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| FFPE Tissue (cont'd)              | Detection of the following: (cont'd)                                                                                                      | <u>Immunohistochemistry</u><br>Automated methods (cont'd)<br>Bond III IHC instruments and in-house procedures:<br>CP-HiSD-SOP-ICC<br>CP-HiSD-SOP-36 |               |
|                                   | Lymphatic endothelium                                                                                                                     | Factor VIII                                                                                                                                         |               |
|                                   | Fibrohistiocytic Tumour                                                                                                                   | Factor XIIIa                                                                                                                                        |               |
|                                   | Erythroid cells, erythroleukemia                                                                                                          | Glycophorin A                                                                                                                                       |               |
|                                   | Hepatocellular carcinomas(HCC), yolk sac tumours                                                                                          | Glypican-3                                                                                                                                          |               |
|                                   | Cytotoxic T cells granules                                                                                                                | Granzyme B                                                                                                                                          |               |
|                                   | Smooth muscle                                                                                                                             | h-Caldesmon                                                                                                                                         |               |
|                                   | Trophoblasts                                                                                                                              | HCG                                                                                                                                                 |               |
|                                   | GVHD Skin                                                                                                                                 | HLA-DP, DQ, DR                                                                                                                                      |               |
|                                   | Melanosomes                                                                                                                               | HMB 45                                                                                                                                              |               |
|                                   | Helicobacter pylori                                                                                                                       | H. pylori                                                                                                                                           |               |
|                                   | Alpha chains                                                                                                                              | IgA (renal)                                                                                                                                         |               |
|                                   | Gamma chains                                                                                                                              | IgG (renal)                                                                                                                                         |               |
|                                   | Mu chains                                                                                                                                 | IgM (renal)                                                                                                                                         |               |
|                                   | Immunoglobulin G                                                                                                                          | IgG                                                                                                                                                 |               |
|                                   | IgG4 related disease                                                                                                                      | IgG4                                                                                                                                                |               |



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| HUMAN TISSUES AND FLUIDS (cont'd) | <u>Histopathology (cont'd)</u><br>Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd) | Macroscopic and microscopic examination using documented in-house procedures in conjunction with manufacturer's instructions (where relevant)       | A             |
| FFPE Tissue (cont'd)              | Detection of the following: (cont'd)                                                                                                      | <u>Immunohistochemistry</u><br>Automated methods (cont'd)<br>Bond III IHC instruments and in-house procedures:<br>CP-HiSD-SOP-ICC<br>CP-HiSD-SOP-36 |               |
|                                   | Sex chord stromal tumours                                                                                                                 | Inhibin                                                                                                                                             |               |
|                                   | Islets of Langerhans tumours                                                                                                              | Insulin                                                                                                                                             |               |
|                                   | Cell proliferation marker                                                                                                                 | Ki 67                                                                                                                                               |               |
|                                   | Breast cancer                                                                                                                             | Mammoglobin                                                                                                                                         |               |
|                                   | Melanocytes                                                                                                                               | MELAN-A                                                                                                                                             |               |
|                                   | Melanocytes (triple antibody cocktail pan melanoma screen)                                                                                | Melanoma cocktail                                                                                                                                   |               |
|                                   | Broad range cytokeratin                                                                                                                   | MNF116                                                                                                                                              |               |
|                                   | B-cells                                                                                                                                   | MUM-1                                                                                                                                               |               |
|                                   | Myeloid cells                                                                                                                             | Myeloperoxidase                                                                                                                                     |               |
|                                   | Classification of rhabdomyosarcoma                                                                                                        | Myo-D1                                                                                                                                              |               |
|                                   | Classification of rhabdomyosarcoma and Wilms tumours                                                                                      | Myogenin                                                                                                                                            |               |
|                                   | Skeletal and cardiac muscle                                                                                                               | Myoglobin                                                                                                                                           |               |
|                                   | Neuroblastoma cells                                                                                                                       | Neuroblastoma 84A                                                                                                                                   |               |
|                                   | Classification of tumours with neuronal differentiation                                                                                   | Neurofilament protein (NFP)                                                                                                                         |               |



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| HUMAN TISSUES AND FLUIDS (cont'd) | <u>Histopathology (cont'd)</u><br>Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd) | Macroscopic and microscopic examination using documented in-house procedures in conjunction with manufacturer's instructions (where relevant)       | A             |
| FFPE Tissue (cont'd)              | Detection of the following: (cont'd)                                                                                                      | <u>Immunohistochemistry</u><br>Automated methods (cont'd)<br>Bond III IHC instruments and in-house procedures:<br>CP-HiSD-SOP-ICC<br>CP-HiSD-SOP-36 |               |
|                                   | Neuroendocrine marker                                                                                                                     | Neuro specific Endolase (NSE)                                                                                                                       |               |
|                                   | Seminoma                                                                                                                                  | OCT-2                                                                                                                                               |               |
|                                   | Germ Tumour cells                                                                                                                         | OCT3/4                                                                                                                                              |               |
|                                   | Tumour suppressor gene                                                                                                                    | P53                                                                                                                                                 |               |
|                                   | mRNA/ p16 HPV biomarkers                                                                                                                  | P16                                                                                                                                                 |               |
|                                   | mRNA/P16 HPV biomarkers                                                                                                                   | P16                                                                                                                                                 |               |
|                                   | Basal cell marker                                                                                                                         | P63                                                                                                                                                 |               |
|                                   | ALL                                                                                                                                       | Pax 5                                                                                                                                               |               |
|                                   | Ovarian serous carcinoma, clear cell renal cell carcinoma, papillary thyroid carcinoma                                                    | PAX8                                                                                                                                                |               |
|                                   | Follicular helper T cells                                                                                                                 | PD-1                                                                                                                                                |               |
|                                   | Placental alkaline phosphatase                                                                                                            | PLAP                                                                                                                                                |               |
|                                   | Prostatic intraepithelial neoplasia                                                                                                       | PIN cocktail                                                                                                                                        |               |
|                                   | Placental alkaline phosphatase                                                                                                            | PLAP                                                                                                                                                |               |
|                                   | Prostatic specific antigen                                                                                                                | PSA                                                                                                                                                 |               |



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| HUMAN TISSUES AND FLUIDS (cont'd) | <u>Histopathology (cont'd)</u><br>Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd) | Macroscopic and microscopic examination using documented in-house procedures in conjunction with manufacturer's instructions (where relevant)       | A             |
| FFPE Tissue (cont'd)              | Detection of the following: (cont'd)                                                                                                      | <u>Immunohistochemistry</u><br>Automated methods (cont'd)<br>Bond III IHC instruments and in-house procedures:<br>CP-HiSD-SOP-ICC<br>CP-HiSD-SOP-36 |               |
|                                   | Melanoma, neuroendocrine cells                                                                                                            | S100                                                                                                                                                |               |
|                                   | Smooth muscle cells                                                                                                                       | Smooth muscle actin                                                                                                                                 |               |
|                                   | SV40 infected cells                                                                                                                       | SV40                                                                                                                                                |               |
|                                   | Neuroendocrine marker                                                                                                                     | Synaptophysin                                                                                                                                       |               |
|                                   | Early B-Cell, thymocyte marker                                                                                                            | TdT                                                                                                                                                 |               |
|                                   | Lumen of thyroid follicles                                                                                                                | Thyroglobulin                                                                                                                                       |               |
|                                   | Cytotoxic T cell granule.<br>Anaplastic large cell lymphoma                                                                               | TIA-1                                                                                                                                               |               |
|                                   | Levels of Trypsin in pancreas                                                                                                             | TRYPSIN                                                                                                                                             |               |
|                                   | Thyroid transcription factor-1                                                                                                            | TTF-1                                                                                                                                               |               |
|                                   | Mesenchymal marker                                                                                                                        | Vimentin                                                                                                                                            |               |
|                                   | Wilms Tumour gene product                                                                                                                 | Wilms Tumour                                                                                                                                        |               |



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|----------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| <p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>FFPE Tissue (cont'd)</p> | <p><u>Histopathology (cont'd)</u></p> <p>Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd)</p> <p>Detection of the following: (cont'd)</p> <p>Cancer marker</p> <p>Monocytes and macrophages</p> <p>Estrogen Receptor</p> <p>Malignant mesothelioma, colorectal cancer</p> <p>Hepatocellular neoplasms</p> <p>Breast carcinoma</p> <p>Human Herpes virus 8 (Kaposi, AIDS)</p> <p>Hepatocytes</p> <p>Mismatch Repair Protein Expression</p> <p>Mismatch Repair Protein Expression</p> <p>Mismatch Repair Protein Expression</p> <p>Mismatch Repair Protein Expression</p> | <p>Macroscopic and microscopic examination using documented in-house procedures in conjunction with manufacturer's instructions (where relevant)</p> <p><u>Immunohistochemistry</u><br/>Automated method using Roche Ventana Benchmark and in-house procedures:</p> <p>Incorporating the following antibodies:</p> <p>Beta Catenin</p> <p>CD1</p> <p>ER</p> <p>Glut-1</p> <p>Glutamine synthetase</p> <p>Her2</p> <p>HHV8</p> <p>Hepatocyte Specific Antigen (HSA)</p> <p>MLH1</p> <p>MSH1</p> <p>MSH6</p> <p>PMS1</p> | <p>A</p>      |





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| HUMAN TISSUES AND FLUIDS (cont'd) | <u>Histopathology (cont'd)</u><br>Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd) | Macroscopic and microscopic examination using documented in-house procedures in conjunction with manufacturer's instructions (where relevant)         | A             |
| FFPE Tissue (cont'd)              | Detection of the following: (cont'd)                                                                                                      | <u>Immunohistochemistry</u><br>Automated method using Roche Ventana Benchmark and in-house procedures:<br><br>Incorporating the following antibodies: |               |
|                                   | Progesterone Receptor                                                                                                                     | PR                                                                                                                                                    |               |
|                                   | Smooth muscle cells                                                                                                                       | Smooth muscle myosin                                                                                                                                  |               |
|                                   | Mantle Cell lymphoma transcription factor                                                                                                 | SOX11                                                                                                                                                 |               |
| FFPE tissue on glass slides       | Preparation and examination to identify or exclude morphological and cytological abnormalities                                            | <u>In-Situ Hybridisation</u><br>Bond III IHC instruments<br>CP-HiSD-SOP-36<br>CP-HiSD-SOP-BOND                                                        |               |
|                                   | Detection and identification of:                                                                                                          |                                                                                                                                                       |               |
|                                   | Latent EBV infection                                                                                                                      | EBER-ISH                                                                                                                                              |               |
|                                   | Kappa light chains, light chain restriction or monoclonality                                                                              | Kappa-ISH                                                                                                                                             |               |
|                                   | Lambda light chains, light chain restriction or monoclonality                                                                             | Lambda-ISH                                                                                                                                            |               |
|                                   | Herpes simplex virus infected cells                                                                                                       | HSV type I                                                                                                                                            |               |
|                                   | Herpes simplex virus infected cells                                                                                                       | HSV type II                                                                                                                                           |               |



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|-------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| HUMAN TISSUES AND FLUIDS (cont'd)<br><br>Slides prepared in-house from sample types above | <u>Histopathology (cont'd)</u><br><br>Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd)<br><br>Morphological assessment and interpretation/diagnosis | Macroscopic and microscopic examination using documented in-house procedures in conjunction with manufacturer's instructions (where relevant)<br><br>Microscopy (qualitative analysis)<br>In-house procedures:<br><br>CP-QMS-SOP-23 Report content<br>CP-QMS-SOP-25 Double reporting using:<br>Leica DM1000<br>Leica DM2000<br>Leica DM2500<br>Leica DM3000<br>Leica DM4000<br>Leica DMLB<br>Leica DMLB2<br>Leica DMLS<br>Leica DMRB<br>Leica DMR<br>Laborlux S<br>Nikon E600<br>Nikon Eclipse 400<br>Nikon Eclipse 50i<br>Nikon Eclipse 80i<br>Nikon Eclipse Ci-E<br>Nikon Eclipse E400<br>Nikon Eclipse E600<br>Olympus BH2<br>Olympus BX40<br>Olympus BX40CY<br>Olympus BX40CYF2<br>Olympus BX41<br>Olympus BX45<br>Olympus BX45TF<br>Olympus CX40RF200 | A, C          |
| Intraoperative breast surgery sentinel lymph node samples                                 | Detection of Cytokeratin 19 (CK19) mRNA                                                                                                                                                                    | One stop nucleic acid method (OSNA) in-house method<br>CP-NHIS-SOP-266 and CP-NHIS-SOP209-216<br>and:<br>Sysmex RD-1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | B             |



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| Materials/Products tested                                     | Type of test/Properties measured/Range of measurement                                                                                                                                                                                                                                            | Standard specifications/ Equipment/Techniques used                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Location Code |
|---------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| <p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Skin biopsies</p> | <p><u>Histopathology (cont'd)</u></p> <p>Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd)</p> <p>Detection and identification of antigens and antibodies:</p> <p>IgA</p> <p>IgG</p> <p>IgM</p> <p>C3 Complement</p> <p>C1q Complement</p> | <p>Macroscopic and microscopic examination using documented in-house procedures in conjunction with manufacturer's instructions (where relevant)</p> <p>Using Leica CM1950 Microtome and Leica microscope with UV attachment and filters to enable viewing of fluorescein isothiocyanate (FITC) with in-house procedures:<br/>CP-HiSD-SOP-6<br/>CP-HiSD-SOP-27</p> <p>FITC conjugated anti Human IgA</p> <p>FITC conjugated anti Human IgG</p> <p>FITC conjugated anti Human IgM</p> <p>FITC conjugated anti Human C3</p> <p>FITC conjugated anti Human C1q</p> | <p>A</p>      |



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| Materials/Products tested                                                                                                                                                                                                      | Type of test/Properties measured/Range of measurement                                                                                                                                                                                                  | Standard specifications/ Equipment/Techniques used                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Location Code |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| <p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Cervical Cytology samples (Gynae)Cervical/Vaginal cells</p> <p>Slides prepared in-house from sample types listed above</p> <p>Cervical Cytology samples Vaginal/Cervical cells</p> | <p><u>Gynaecological Cytology</u></p> <p>Preparation and screening to identify or exclude morphological and cytological abnormalities (cont'd)</p> <p>Morphological assessment and interpretation/diagnosis</p> <p>Detection of high-risk HPV mRNA</p> | <p><u>Liquid based Cytology processing</u><br/>Automated method using T5000 processor and in-house procedure: CP-CyCer-SOP-41<br/>T2000 processor CP-CyCer-SOP-4<br/>Leica ST5020/CV5030 stainer and coverslipper CP-CyCer-SOP-42<br/>CP-CyCer-SOP-43</p> <p><u>Papanicolaou staining</u><br/>CP-CyCER-SOP58</p> <p><u>Microscopy qualitative analysis</u><br/>In-house procedures: CP-CyCER-SOP-76 using microscopes listed above</p> <p>Hologic Tomcat aliquotter and Hologic Panther Nucleic Acid Amplification Test (NAAT) using APTIMA HPV Assay and in-house procedure: CP-CyMol-SOP-14</p> | <p>A</p>      |



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|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| <p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Fluids<br/>Brushings<br/>Imprints,<br/>Fine-needle aspirations<br/>CSF<br/>Urine</p> <p>Slides prepared from sample types listed above</p> <p>Slides prepared from sample types listed above</p> <p>Synovial fluid</p> <p>Stained slides prepared in-house from sample types above</p> | <p><u>Diagnostic Cytology</u></p> <p>Preparation and screening to identify or exclude morphological and cytological abnormalities (cont'd)</p> <p>Identification of crystals:<br/>Monosodium urate<br/>Calcium pyrophosphate<br/>Basic Calcium Phosphate<br/>Cholesterol</p> <p>Morphological assessment and Interpretation/diagnosis above</p> | <p><u>Preparation/Centrifugation</u><br/>Manual method using:</p> <p>Hettich Rotina 46 centrifuge and in-house procedure:<br/>CP-CyNG-SOP-4</p> <p>Thermo Shandon Cytospin4 cytocentrifuge and in-house procedure:<br/>CP-CyNG-SOP-36</p> <p><u>Papanicolaou staining</u></p> <p>Automated method using Leica ST5020/CV5030 Stainer and Coverslipper<br/>And in-house procedures:<br/>CP-CyNG-SOP-36<br/>CP-CyNG-SOP-42</p> <p><u>Romanowsky Stains:</u><br/>Giemsa and May Grunwald<br/>Giemsa<br/>CP-CyNG-SOP-7</p> <p>Polarising microscopy manual method using:<br/>Leica DMLB microscope with compensated polarised filter and in-house procedure:<br/>CP-CyNG-SOP-57</p> <p><u>Microscopy (qualitative analysis)</u><br/>in house procedure<br/>CP-CyNG-SOP-57 and microscopes listed above</p> | <p>A</p>      |
| END                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |               |