# Schedule of Accreditation

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# United Kingdom Accreditation Service

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**9927**

**Accredited to ISO 15189:2022**

## Bolton NHS Foundation Trust

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**Cellular Pathology and Andrology**
**Bolton Royal Hospital**
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**Testing performed at the above address only**

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

**Site activities performed away from the laboratory:**

| Location details | Activity |
|---|---|
| Mortuary<br>Bolton Royal Hospital<br>Minerva Road<br>Farnworth<br>Bolton<br>BL4 0JR<br>United Kingdom | Mortuary Services (body receipt, storage and release) |

DETAIL OF ACCREDITATION

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|---|---|---|
| HUMAN BODY SAMPLES | Histopathological examination activities for the purposes of clinical diagnosis | In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: |
| Tissue: biopsy, excision, resection and post-mortem specimens | Examination of tissues to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis | Specimen dissection<br>SOP:HY-SOP-PATH-100, HY-SOP-CU-0013,<br>AFOS Downdraft benches<br>SOP: HY-SW-CU-008<br><br>Tissue processing using Epredia REVOS and Sakura VIP6 Tissue processors<br><br>SOP;<br>HY-PROC-SW-11<br>HY-PROC-SW-12<br>HY-PROC-SW-9<br><br>Sakura Tissue Tek TEC 6 Tissue Embedding centres<br><br>SOP:<br>HY-SOP-MLAB-0010 |
| Femoral head, bone reamings | | Decalcification Pathvision Faxitron<br>SOP: HY-SOP-CU-0021<br>HY-PROC-SOP-1 |
| Frozen sections: Parathyroid and other excisional/resection tissue removed from body | | Cryotomy Intra-operative Frozen sections Leica CM1860UV Cryostat<br><br>SOP:<br>HY-SOP-CU-0010 |
| Formalin Fixed Paraffin Embedded (FFPE) wax blocks of processed tissue. | | Leica/Epredia Tissue Sectioning Microtomes<br>SOP: HY-SOP-MLAB-0011 |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|---|---|---|
| HUMAN BODY SAMPLES (cont'd) | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: |
| FFPE slides | | Interpretive/diagnostic microscopy SOP: HY-MAIN-SW-7, HY-MAIN-SOP-4, HY-MLAB-DOC-20, HY-MLAB-DOC-28, HM-ESD-11 |
| FFPE (Formalin fixed paraffin embedded) slides | Routine morphological staining for the detection of: | |
| | Identification of nuclei, cell cytoplasm and most connective tissues in cells and tissues | Sakura Tissue Tek DRS 2000 stainer<br>Haematoxylin & Eosin stain<br>Manual and Automated<br>SOPs: HY-SOP-MLAB-0003; HY-SOP-SS-0029 |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|---|---|---|
| HUMAN BODY SAMPLES (cont'd) | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: |
| FFPE (Formalin fixed paraffin embedded) slides | Special stains for the detection of: | Documented in-house procedures for manual special stains |
| | Acid mucopolysaccharides | Alcian Blue, Ph 2.5, SOP: HY-SOP-SS-0001 |
| | Acid and Neutral Mucopolysaccharides | Alcian Blue/PAS SOP: HY-SOP-SS-0002 |
| | Acid and Neutral Mucopolysaccharides, no glycogen | Alcia Blue/PAS Diastase SOP: HY-SOP-SS-0003 |
| | Differentiation of glycogen from mucin | PAS + Diastase digestion SOP: HY-SOP-SS-0005 |
| | Neural Mucins/glycogen | PAS SOP: HY-SOP-SS-0012 |
| | Elastic fibres, muscle, collagen | Millers elastic stain SOP: HY-SOP-SS-0007 |
| | Amyloid | Congo Red SOP: HY-SOP-SS-0008 |
| | Fungal hyphae / yeast bodies | Grocott-Gomori Methanamine Silver SOP: HY-SOP-SS-0009 |
| | Pneumocysts | Grocott Modified for Pneumocystis, SOP: HY-SOP-SS-0010 |
| | H. pylori, connective tissue | Giemsa stain, Gurr's Improved SOP: HY-SOP-SS-0013 |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|---|---|---|
| HUMAN BODY SAMPLES (cont'd) | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: |
| FFPE (Formalin fixed paraffin embedded) slides (cont'd) | Special stains for the detection of: (cont'd) | Documented in-house procedures for manual special stains |
| | Differentiation of Gram positive and Gram negative organisms | Gram stain<br>SOP: HY-SOP-SS-0014 |
| | Melanin, Argentaffin, Chromaffin and some Lipofuscins, | Masson Fontana<br>SOP: HY-SOP-SS-0015 |
| | Copper Associated Protein | Shikata's Orcein<br>SOP: HY-SOP-SS-0019 |
| | Haemosiderin | Perl's Prussian Blue<br>SOP: HY-SOP-SS-0021 |
| | Reticular fibres | Gordon & Sweet's Reticulin<br>SOP: HY-SOP-SS-0022 |
| | Mast cells | Toluidine Blue<br>SOP: HY-SOP-SS-0023 |
| | M. leprae | Ziehl Nielson modified<br>SOP: HY-SOP-SS-0027 |
| | Tubercle bacilli | Ziehl Nielson<br>SOP: HY-SOP-SS-0026 |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|---|---|---|
| HUMAN BODY SAMPLES (cont'd) | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: |
| FFPE (Formalin fixed paraffin embedded) slides | Immunocytochemistry examination activities to detect the following: | Roche Ventana Benchmark Ultra SOP: HY-SOP-ICC-0009 |
| | Glandular and stratified squamous epithelium | AE1/AE3 |
| | Embryonic Cells in normal tissue and germ tumours | AFP, Alpha -1-Fetoprotein |
| | Follicular and diffused large cell lymphomas from reactive lymph nodes | bcl-2 Oncoprotein |
| | Reed Sternberg cells in Hodgkin's lymphoma, anaplastic large cell lymphoma and plasma cells | Ber H2, CD30 |
| | Epithelial Cells of the Colon | Ber EP4 |
| | Classification of mesothelial cells and malignant mesothelioma of the epithelial type | Calretinin |
| | Carcinomas from malignant tumours of non-epithelial origin | CAM 5.2 |
| | All germinal centre cells – tonsil Renal cell carcinoma | CD10 CALLA |
| | KIT protein in gastro-intestinal stromal tumours | CD117, c-KIT, GIST tumour marker, |
| | CD138, B cell differentiation | CD138 |
| | Normal and neoplastic T cells from thymocytes to mature T cells | CD3, T Cell |
| | Neural / neuroendocrine tissue and natural killer cells | CD56, NCAM, Neural Adhesion |
| | Macrophages | CD68, Macrophage |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|---|---|---|
| HUMAN BODY SAMPLES (cont'd) | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: |
| FFPE (Formalin fixed paraffin embedded) slides (cont'd) | Immunocytochemistry examination activities to detect the following (cont'd): | Roche Ventana Benchmark Ultra SOP: HY-SOP-ICC-0009 |
| | B cells all stages | CD79a, B Cell |
| | Loss of differentiation in colorectal cancers | CDX2 |
| | Adenocarcinoma | CEA, Carcinoembryonic Antigen |
| | Neuroendocrine cells | Chromogranin |
| | Adenocarcinomas of breast, lung, endometrium, ovary, thyroid and carcinomas of bladder and renal cell | CK7, Cytokeratin 7 |
| | Columnar cell epithelium | CK20, Cytokeratin 20 |
| | Myoepithelial cells of the prostate / breast. Squamous cell carcinoma | CK 5/6, Cytolkeratin 5/6 |
| | Cytomegalovirus infected cells | Cytomegalovirus, CMEG |
| | Smooth and striated muscle tumours | Desmin |
| | Cell Proliferation | Dual p63-P504S |
| | Membrane markers | D2-40 (Podoplanin) |
| | Adenocarcinoma from mesothelioma and ductal vs lobular cancer of the breast | E-Cadherin |
| | Variety of normal and neoplastic epithelia | EMA, Epithelial Membrane Antigen |
| | Breast carcinoma and urothelial carcinoma | GATA3 |
| | HER-2 expressing cells in breast cancer | HER-2 |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|---|---|---|
| HUMAN BODY SAMPLES (cont'd) | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: |
| FFPE (Formalin fixed paraffin embedded) slides (cont'd) | Immunocytochemistry examination activities to detect the following (cont'd): | Roche Ventana Benchmark Ultra SOP: HY-SOP-ICC-0009 |
| | Melanoma cells | HMB45 |
| | Thyroid cancer | HBME-1 |
| | Hepatocellular cancer | Hep PAR1 |
| | Endothelial cells. Benign and malignant vascular disorders | JC70A or CD31 |
| | B cells | L26, B Cell, CD20 |
| | All Leucocytes | LCA, CD45 |
| | Melanomas and angiomyolipomas | MART-1 (Melan A) |
| | Proliferating cells | MIB-1 Proliferating Cell Marker |
| | Neoplastic tissue | Napsin |
| | Prostate cancer | NKX3 |
| | Oestrogen receptors breast carcinoma | Oestrogen Receptor (OR) |
| | Prostatic carcinoma | P504S, Clone 13H4 |
| | Malignant change in cervical epithelium, HPV | P16 |
| | Cell proliferation | P63 |
| | Ovarian carcinoma, renal cell carcinoma and thyroid carcinoma | PAX8 |
| | P40 protein | P40 |
| | Wild type mutant p53 | P53 |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|---|---|---|
| HUMAN BODY SAMPLES (cont'd) | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: |
| FFPE (Formalin fixed paraffin embedded) slides (cont'd) | Immunocytochemistry examination activities to detect the following (cont'd): | Roche Ventana Benchmark Ultra SOP: HY-SOP-ICC-0009 |
| | Breast carcinoma | Progesterone Receptor (PR) |
| | Vascular and leucocyte differentiation | QBend10 (CD34) |
| | Renal cell carcinoma | RCC |
| | Malignant melanocytic tumours of the skin and metastases of human malignant melanomas | S100 |
| | Smooth muscle cells, myofibroblasts and myoepithelial cells | Smooth Muscle Actin (SMA) |
| | Neuroendocrine and Epithelial neoplasms | Synaptophysin |
| | Follicular epithelial cells of thyroid, Type II pneumocytes ie; smooth muscle, endothelium, lymphocytes | Thyroid Transcription Factor (TTF1) |
| | Cells of mesenchymal origin | Vimentin |
| | Mesenchymal cells, Wilms tumour, Serous ovarian adenocarcinoma | WT-1 |
| Slides prepared as above | Morphological assessments and interpretation/diagnosis | Leica DM4B/DMRB/DM2000, Olympus BX40/41 and Nikon Eclipse 80C microscopes<br>SOPs: HY-SOP-PATH-0001, HY-MAIN-SOP-4, HY-MLAB-DOC-20, HY-MLAB-DOC-28, HM-ESD-11, HY-MAIN-SW-7, HY-MAIN-SW-6 |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|---|---|---|
| HUMAN BODY SAMPLES | Cytology (Non-Gynae) examination activities for the purposes of clinical diagnosis | In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: |
| Fine needle aspirates –<br>Bronchial Brushings,<br>Serous fluids,<br>Sputum,<br>Bronchial washings,<br>Urine | Preparation and examination of cellular material to identify or exclude morphological and cytological abnormalities | In-house procedures in conjunction with manufacturer's instructions using:<br><br>Hettich Rotina 380 centrifuge<br>SOP: CY-SW-1<br>Thermo Shandon Cytospin<br>SOP: NC-SOP-STAIN-0003<br>Class I Biological Safety cabinet<br>SOP: CY-NG-SW-3<br>Light microscopes<br>SOPs: HY-MAIN-SW-6, HY-MAIN-SW-7<br><br>Non-gynae specimen preparation, examination and reporting<br>SOPs: NC-SOP-LAB-0007; CY-NG-SOP-2; CY-NG-SOP-3; NC-SOP-LAB-0012 |
| Serous Fluids including Pleural fluids | | NC-SOP-LAB-0017 – Specimen Preparation – Aspirated Fluid. |
| Sputum and Bronchial Washings | | NC-SOP-LAB-0013 - Specimen Preparation - Sputum,<br>NC-SOP-LAB-0007 – Specimen Preparation – Bronchial Washings |
| Urine | | NC-SOP-LAB-0015 - Specimen Preparation - Urines |
| FNAs and Brushings | Demonstration of Cells (nuclei and cytoplasm) and micro-organisms | CY-NG-SOP-3 Specimen Preparation FNA, Brushings and Direct Smears |
| Non-gynae Cytology Preparations and Staining | Cellular morphological abnormalities | Papanicolaou stain using the Gemini AS stainer<br>SOP: CY-SW-2<br>Preparing an Agar Block NC-SOP-LAB-0001 |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|---|---|---|
| HUMAN BODY SAMPLES (cont'd) | Cytology (Non-Gynae) examination activities for the purposes of clinical diagnosis (cont'd) | In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: |
| Non-gynae cytology preparations on glass slides | Malignant Cells | Giemsa Staining (Hema-Gurr) SOP: NC-SOP-STAIN-0011 |
| Slides prepared as above | Morphological assessments and interpretation/diagnosis | Using light microscopy- Leica DM4B/DMRB/DM2000, Olympus BX40/41 and Nikon Eclipse 80C microscopes SOPs: HY-MAIN-SW-6, HY-MAIN-SOP-4, HY-MAIN-SW-7 |
| HUMAN BODY SAMPLES | Andrological examination activities for the purposes of clinical diagnosis | |
| Semen | Post vasectomy: | Based on 2016 Laboratory guidelines for post vasectomy semen analysis: Association of Biomedical Andrologists, the British Andrology Society and the British Association of Urological Surgeons) |
| | Detection of sperm | Manual method using large volume chambers/manual microscopy and documented in-house procedure: Post Vasectomy Semen Analysis SOP: CY-AND-SOP -1 |
| | 1-hour Post Vasectomy:<br>Detection of sperm<br>Sperm concentration<br>Sperm motility | Manual method using large volume chambers/manual microscopy and documented in-house procedure: 1hour Post Vasectomy Semen Analysis CY-AND-SOP-2 |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|---|---|---|
| HUMAN BODY SAMPLES (cont'd) | Andrological examination activities for the purposes of clinical diagnosis (cont'd) | |
| Semen (cont'd) | Fertility testing: | Based on WHO laboratory manual for the examination and processing of human semen (Sixth edition 2021) and manual method / documented in-house procedure SOPs: NC-SOP-AND-0002, 0004, 0005, 0006 |
| | Volume | Volume/weight |
| | pH | Colorimetric strips |
| | Sperm morphology including TZI scoring | Stained slides (Papanicolau) using the Gemini AS stainer and microscopy (Bright field) SOP: CY-SW-2 |
| | Sperm concentration | Improved Neubauer counting chambers and Microscopy (Phase contrast) |
| | Sperm motility | Microscopy (Phase contrast) |
| | Sperm vitality | Stained slide (Eosin/Nigrosin dye exclusion test) microscopy (Bright field) |
| END | | |