

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

| | | |
|--|---|---|
|  UKAS MEDICAL 9587 Accredited to ISO 15189:2012 | North Tees and Hartlepool NHS Foundation Trust Issue No: 005 Issue date: 23 May 2020 | |
| | Cellular Pathology University Hospital North Tees Hardwick Stockton on Tees TS19 8PE | Contact: Joanne Wintrip Tel: +44 (0)1642 624101 E-Mail: Joanne.Wintrip@nth.nhs.uk Website: www.nth.nhs.uk |
| Testing performed at the above address only | | |

Site activities performed away from the locations listed above:

| Location details: | Activity | Location code |
|---|-------------------|---------------|
| Address: Mortuary University Hospital North Tees Hardwick Stockton on Tees | Mortuary services | N/A |
| Address: University Hospital of Hartlepool Holdforth Road Hartlepool Cleveland TS24 9AH | Body Store | N/A |



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DETAIL OF ACCREDITATION

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|---|---|--|
| <p>HUMAN TISSUES AND FLUIDS</p> <p>Tissue: biopsy, excision, resection and post mortem specimens</p> | <p><u>Histological examination activities for the purpose of clinical diagnosis</u></p> <p>Examination of tissue samples in order to identify or exclude morphological abnormality for the purpose of diagnosis</p> | <p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Specimen dissection using SOP NTH_HIS_213, NTH_HIS_214, NTH_HIS_215, NTH_HIS_216, NTH_HIS_217, NTH_HIS_218</p> <p>Tissue Processing Using Peloris tissue processor and Leica embedder and SOP NTH_HIS_188 and NTH_HIS_176</p> <p>Tissue embedding using Leica embedding stations and SOP NTH_HIS_092</p> <p>Microtomy using Leica microtomes and SOP NTH_HIS_079</p> <p>Cryotomy using Leica cryostat and SOP NTH_HIS_093</p> |
| <p>FFPE slides</p> | <p>Routine morphological staining for the detection of:</p> <p>Basophilic and eosinophilic structures</p> | <p>Routine morphological staining Using Sakura TissueTek Prisma automated H&E staining and NTH_HIS_226</p> |
| <p>Frozen Section</p> | | <p>Manual staining for Rapid H&E Using NTH_HIS_226</p> |



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| HUMAN TISSUES AND FLUIDS (cont'd) | <u>Histological examination activities for the purpose of clinical diagnosis</u> (cont'd) | In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: |
| FFPE slides | Immunohistochemistry to detect the following: Smooth muscle and tumours Liver marker Epithelial marker Pan B cell marker T-cell lymphocytes Epithelial marker Ovarian tumour marker Epithelial marker Medullary thyroid tumour marker Smooth muscle marker Smooth muscle marker Mesothelioma marker Secretory epithelial marker Follicular lymphoma Hodgkin's lymphoma GI tumours Reed Sternberg cells Endothelial cells Neuroendocrine marker Macrophage marker Intestinal epithelium Adenocarcinoma marker Neuroendocrine marker G I tract epithelium Small bowel/stomach epithelium Basal epithelial cells Basal epithelial cells Breast, lung ,endometrial Ca Gastro intestinal stromal tumour Basal epithelium Muscular filaments Epithelial cells Breast tumours (hormone receptor) Dermatofibroma marker Endothelial cells Breast and urothelial carcinoma Germ cell tumour marker | NTH_HIS_223 Using the Ventana Benchmark XT: Actin AFP AMACR antibody B Cell CD20 Bcl-2 Ber EP4 Ca125 Cadherin Calcitonin Caldesmon Calponin Calretinin CAM 5.2 CD10 CD15 CA19.9 CD30 CD34 CD56 CD68 CDX-2 CEA Chromogranin CK19 CK20 CK34 CK5 CK7 C-kit (CD117) Collagen iv Desmin EMA ER Factor 13a Factor VIII GATA 3 HCG |



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| HUMAN TISSUES AND FLUIDS (cont'd) | <u>Histological examination activities for the purpose of clinical diagnosis</u> (cont'd) | In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: |
| FFPE slides | Immunohistochemistry to detect the following (cont.): | NTH_HIS_223 Using the Ventana Benchmark XT: |
| FFPE slides | Indicates suitability for Herceptin therapy Melanocytic cells Granulosa cell and mucinous epithelial ovarian tumours | Her2 HMB45 (Melanosome) Inhibin |
| FFPE slides | Proliferation marker Basement Membrane Haematopoietic cells Breast tumour marker Melanocytic marker Micrometastatic tumour, rule out lymphoma Smooth muscle Neuroendocrine marker Thyroid tumours HPV marker Prostatic and breast tumour marker Tumour suppressor gene Basal cell epithelium Germ cell tumour marker Breast tumour marker Prostatic tumour/metastasis marker Prostatic tumour/metastasis marker Renal cell carcinoma Melanoma and nerve cell marker Neuroendocrine marker T cells, myeloma cells Thyroid follicular carcinoma Lung, thyroid tumours Vascular smooth muscle, mesenchymal tumour marker Wilm's and mesothelioma tumour marker | Ki 67 Laminin LCA (CD 45) Mammaglobin Mel A Mulit (Pan) CK (AE1/AE3) Myosin NSE Pax 8 P16 P40 P53 P63 PLAP PR PSA PSAP RCC S100 Synaptophysin TCell (CD43) Thyroglobulin TTF-1 Vimentin WT1 |



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| HUMAN TISSUES AND FLUIDS (cont'd) | <u>Histological examination activities for the purpose of clinical diagnosis</u> (cont'd) | In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: |
| FFPE slides | Manual Staining to detect the following : | NTH_HIS_226 Using the Ventana Benchmark XT: |
| FFPE slides | Differentiates sulphated acid mucins, neutral mucins and mixed mucins Differentiates sulphated acid and neutral mucins | Alcian Blue Diastase PAS Alcian Blue PAS |
| FFPE slides | Amyloid Neutral mucins, glycogen Vascular invasion of colorectal tumours Melanin, argentaffin granules Helicobacter pylori Bacterial deposits Fungi Basic tissue structure, overt tumour Acid mucins Fibrin Muscle, collagen Melanocytes Elastic fibres Glycogen, fungal walls Haemosiderin Reticulin fibres Hepatitis B surface antigen | Congo Red Diastase PAS Elastin H&E Fontana (Gomori-Burtner) Giemsa Gram Grocott Methenamine Silver (GMS) Haematoxylin and Eosin Hales Dialysed Iron Martius Scarlet Blue (MSB) Massons trichrome Melanin Bleach Millers Elastic (EVG) PAS Perls Reticulin Shikata's Orcein |
| Slides prepared in-house from sample types listed above | Collagen, muscle Osteoid components Tubercle bacilli Morphological assessment and interpretation/diagnosis | Van Gieson Von Kossa Ziehl Neelsen Microscopy (qualitative analysis) In-house procedures: NTH_HIS_082 using: Leica, Nikon and Olympus microscopes |



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| <p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Non- Gynae Cytology Samples including urine, FNA, Fluids, EBUS</p> <p>Slides prepared in-house from sample types listed above</p> | <p><u>Cytopathology (non-gynae) examination activities for the purpose of clinical diagnosis</u></p> <p>Examination of cells to identify or exclude cytological abnormalities for the purpose of diagnosis</p> <p>Morphological assessment and interpretation/diagnosis</p> | <p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Using Thinprep T2000 processor and Leica autostainer for MGG and Papanicolaou staining: NTH_CYT_58 NTH_CYT_61 NTH_CYT_55. NTH_CYT_57 NTH_CYT_54 NTH_CYT_49 NTH_CYT_56 NTH_CYT_42</p> <p>Microscopy (qualitative analysis) In-house procedures: NTH_HIS_082 using: Leica, Nikon and Olympus microscopes</p> |
| END | | |