


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

| | | |
|--|--|--|
|  Accredited to ISO 15189:2012 | NHS Highland | |
| | Issue No: 004 Issue date: 08 September 2021 | |
| | Cellular Pathology Department Zone 3 Raigmore Hospital Old Perth Road Inverness IV2 3UJ | Contact: Jo Brook Tel: +44 (0) 1463 704265 E-Mail: joanne.brook1@nhs.scot |
| Testing performed at the above address only | | |

Locations covered by the organisation and their relevant activities

Activities performed at other sites:

| Location details | | Activity |
|------------------|-----------------|--------------|
| Mortuary | Zone 6 As above | Body Storage |



9611
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

NHS Highland
Issue No: 004 Issue date: 08 September 2021

Testing performed at main address only

DETAIL OF ACCREDITATION

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|--|--|--|
| HUMAN BODY FLUIDS and TISSUES | <u>Diagnostic Cytology examinations to assist in clinical investigations</u> | In House documented procedure & manufacturer's instructions using the following equipment: |
| Wet fixed Preparations. Body fluids, urine, , aspirates, washings, brushings, | Detection of abnormal cells | Processing and Staining using Papanicolou & May Grunwald/ Giemsa Manual Methods using documented procedures in C-PREP-001, C-STAIN-001 |
| Air Dried Preparations. Body fluids, CSFs | | Documented procedure C-EQP-001 Hologic T2000 Centrifuge Cytospin Leica Autostainer XL staining machine Leica 5030 coverslipper Microscopes |
| FNA Wet fixed Preparations: breast, thyroid, lymph node etc | | |
| FNA Air Dried Preparations: breast, thyroid, lymph node etc | | |
| Slides prepared in house as above | <u>Morphological assessment and interpretation/diagnosis</u> | Microscopy Reporting of Pathology Specimens SOP D-CLIN-001, D-CLIN-002 |
| | <u>Frozen Section Histology Examinations & Touch Preparations to assist in clinical investigations</u> | In House documented procedure & manufacturer's instructions using the following |
| Tissue samples | | Manual methods using H&E stain and documentation Manual method using documented procedure in H-SPEC-002 & H-SPEC-005 |
| | Detection of abnormal cells | Leica CM 1850UV CryostatSOPs- H-SPEC-024 |
| | <u>Routine Histopathology examinations to assist in clinical investigations</u> | In House documented manual methods and manufacturer's instructions |
| | | Specimen Dissection Manual method using documented procedures in the range Pathology |



9611
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

NHS Highland
Issue No: 004 Issue date: 08 September 2021

Testing performed at main address only

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|--|---|--|
| HUMAN BODY FLUIDS and TISSUES (cont'd) | <u>Routine Histopathology examinations to assist in clinical investigations (cont'd)</u> | In House documented procedure of manual methods using the following |
| Tissue samples (cont'd) | | Decalcification of tissue sample included in H-SPEC-002 |
| | | Tissue processing Documented procedure & manufacturer's instructions using Thermo Shandon Excelsior H-SPEC-003 & H-SPEC-009 & H-SPEC-008. |
| | | Tissue embedding using Thermo Shandon Histostar H-EMBE-001 & H-EMBE-002 |
| | | Tissue sectioning (Microtomy) Manual method, documented procedure using Leica Microtomes RM2235. H-MAIN-001, H-MAIN-002, H-MAIN-008 & H-MAIN-017 |
| | Identification of basophilic and eosinophilic structures | Routine staining (H&E) Documented procedure & manufacturer's instructions using Leica Autostainer H-MAIN-001 H-MAIN-010 |
| | <u>Special staining of Histopathology examinations to assist in detection of clinical abnormalities</u> | <i>Manual method & documented procedure using Histology Staining and Mounting Procedures SOP</i> H-MAIN-001, H-MAIN-002, H-MAIN-008 & H-MAIN-021 <i>Reporting SOP</i> D-CLIN-001 & D-CLIN-002 |
| | Acid Fast Tubercle Bacilli | In House documented procedure of manual methods using and Microscopy Manual Methods using documented procedures in series H-STAIN-01 Zeihl Nielson |
| | Amyloid | Puchtler's Congo Red |



9611
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

NHS Highland

Issue No: 004 Issue date: 08 September 2021

Testing performed at main address only

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|--|--|---|
| HUMAN BODY FLUIDS and TISSUES (cont'd) | <u>Special staining of Histopathology examinations to assist in detection of clinical abnormalities (cont'd)</u> | In House documented procedure of manual methods using and Microscopy Manual Methods using documented procedures in series H-STAIN-001 |
| | Basement Membranes | Periodic Acid Methanamine Silver (PAMS) |
| | Basophil/Eosinophil/Neutrophil granules | Giemsa |
| | Calcium | Von Kossa |
| | Connective tissue/Collagen/Muscle | Masson Trichrome Van Gieson |
| | Connective tissue/Collagen/Muscle/Fibrin | Martius Scarlet Blue (MSB) Phosphotungstic Acid Haematoxylin |
| | Elastic Fibres | Elastic Van Gieson Orcein elastic |
| | Fungi | Grocott Gomori Methenamine Silver |
| | Glycogen/Neutral Mucins/Fungi | Periodic Acid Schiff's (PAS) +/- Diastase |
| | Gram +ve & Gram -ve Organisms | Stain Gram Twort |
| | Haemosiderin | Perls Prussian Blue Stain |
| | Helicobacter/Micro-organisms | Modified Giemsa |
| | Hepatitis B affected Cells/Copper associated protein | Shikata's Orcein |
| | Lipid | Oil Red O |
| | Mast Cells | Toluidine Blue |
| | Melanin/Argentaffin Substances | Masson Fontana +/- Bleach |
| | Mycobacterium leprae | Wade-Fite |
| | Reticulin Fibres | Gordon & Sweet's Reticulin |



9611
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

NHS Highland
Issue No: 004 Issue date: 08 September 2021

Testing performed at main address only

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|--|---|--|
| HUMAN BODY FLUIDS and TISSUES (cont'd) | <u>Special staining of Histopathology examinations to assist in detection of clinical abnormalities (cont'd)</u> Spirochetes <u>Morphological assessment and interpretation/diagnosis</u> <u>Immunocytochemistry of Histopathology examinations to assist in detection of clinical abnormalities</u> Normal/neoplastic tissue epithelial in origin pan cytokeratin (broad range) Adenocarcinomas, columnar epithelial cells Anaplastic Large cell Lymphoma's (ALCL's) Apoptosis (Cell Death) B cell follicles B cell lymphomas, germinal centre derived lymphomas B cells B cells <u>Immunocytochemistry of Histopathology examinations to assist in detection of clinical abnormalities</u> B Cells B cells and plasma cells | In House documented procedure of manual methods using and Microscopy Manual Methods using documented procedures in series H-STAIN-001 Warthin Starry Microscopy SOP D-CLIN-001 & D-CLIN-002 In house documented procedures & manufacturer's instructions using Leica Biosystems Bond III Fully automated ICC and ISH stainer AE1/AE3 Cytokeratin 20 ALKinase PD-1 Lambda OCT 02 CD20 (CD20cy) CD79a In house documented procedures & manufacturer's instructions using Leica Biosystems Bond III Fully automated ICC and ISH stainer PAX-5 Kappa |



9611
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

NHS Highland

Issue No: 004 **Issue date:** 08 September 2021

Testing performed at main address only

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|--|--|--|
| HUMAN BODY FLUIDS and TISSUES (cont'd) | <u>Immunocytochemistry of Histopathology examinations to assist in detection of clinical abnormalities (cont'd)</u> B cells lymphomas B cells, follicular lymphomas B cells, plasma cells B cells, some T cells B cell lymphomas Basal cells, filamentous keratins from glandular to stratified squamous, prostate adenocarcinoma Breast carcinoma's expressing HER-2 Breast, Colon, lung and urothelial carcinoma's CEA glycoproteins Cells of mesenchymal origin Complement C4d in allograft rejection Cytomegalovirus Cytotoxic T Lymphocytes, Natural Killer cells Embryonic cells in normal tissues and germ tumours Endothelial cells Epithelial cells Epithelial cells | In house documented procedures & manufacturer's instructions using Leica Biosystems Bond III Fully automated ICC and ISH stainer Bcl-6 Protein Bcl-2 Bob-1 CD23 CD 19 CK, HMW (34BE12) HER-2 P53 (DO-7) CEA Vimentin C4d Cytomegalovirus Granzyme B a-1-Fetoprotein CD31 and FVIII Cytokeratin 14 Cytokeratin 8/18 |



9611
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

NHS Highland
Issue No: 004 Issue date: 08 September 2021

Testing performed at main address only

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|--|---|---|
| HUMAN BODY FLUIDS and TISSUES (cont'd) | <u>Immunocytochemistry of Histopathology examinations to assist in detection of clinical abnormalities</u> (cont'd) | In house documented procedures & manufacturer's instructions using Leica Biosystems Bond III Fully automated ICC and ISH stainer |
| | Epithelial Marker-favours adenocarcinoma | MOC31 |
| | Epithelial cells/predominantly adenocarcinomas | BEREP4 |
| | Endothelial cells/some soft tissue tumours | CD34 |
| | Epithelial cells and smooth muscle in fallopian tube. Wilm's tumour | Wilm's Tumour (WT1) |
| | Epithelial cells including ductal and glandular epithelia | Cytokeratin 19 |
| | Erythrocytes | GLYCO |
| | Expressed in variety tumours | Cyclin D1 |
| | Gastro Intestinal Stromal tumours (GIST) | DOG-1 |
| | Germ cell tumours, seminomas | PLAP |
| | Granulocytes, reed-Sternberg cells | CD15 (Leu-M1) |
| | Hairy cell leukaemia cells | TRAP |
| | Herpes Simplex Virus type 1 | HSV1 |
| | Hepatocytes | HEP PAR |
| | Intestinal epithelial cells, colorectal + other adenocarcinomas | CDX2 |
| | Kaposi sarcoma cells | HHV8 |
| | Langerhans cells | CD1a |
| | Leucocytes | CD45 (LCA) |
| | Lymphatic vessels | D2-40 |



9611
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

NHS Highland
Issue No: 004 Issue date: 08 September 2021

Testing performed at main address only

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|--|---|--|
| HUMAN BODY FLUIDS and TISSUES (cont'd) | <u>Immunocytochemistry of Histopathology examinations to assist in detection of clinical abnormalities (cont'd)</u> | In house documented procedures & manufacturer's instructions using |
| | Lympho-haemopoietic tumours | Leica Biosystems Bond III Fully automated ICC and ISH stainer |
| | Macrophages, monocytes, myeloid cells | MUM1 |
| | Marker for mesotheliomas | CD68 (Routine PG M1) |
| | Mature B cells, Follicular dendritic cells | Calretinin |
| | Mature B cells, follicular dendritic cells, CALLA | CD21 |
| | Mature T cells, T cell Lymphomas | CD10 (CALLA) |
| | Melanoma marker | CD5 |
| | Melanoma, melanocyte differentiation | Melan A |
| | Mismatch repair protein, Lynch Syndrome | HMB45 |
| | Myeloid cells | MLH, MSH2, MSH6, PMS2 |
| | Natural killer cells, neuroendocrine tissues | CD33 Myeloperoxidase |
| | Neuroendocrine cells | CD56 (N-CAM) CD 57 |
| | Normal and neoplastic epithelia | Synaptophysin |
| | Normal duct epithelial cells, ductal carcinoma | Cytokeratin 7 |
| | Normal epithelium, over expression in various cancers | E-Cadherin |
| | Nuclei of cells containing a high level of oestrogen | EMA |
| | | ER |



9611
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

NHS Highland
Issue No: 004 Issue date: 08 September 2021

Testing performed at main address only

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|--|---|---|
| HUMAN BODY FLUIDS and TISSUES (cont'd) | <u>Immunocytochemistry of Histopathology examinations to assist in detection of clinical abnormalities (cont'd)</u> Nuclei of cells showing expression of Progesterone Ovarian epithelial malignancies, seminal vesical carcinoma, anaplastic lymphoma Pan cytokeratin (broad range) Parafoallicular cells in thyroid and medullary thyroid carcinomas Peripheral nerves, neuroendocrine tumours Placental trophoblasts Plasma cells Plasma cells Proliferating Cells Prostate adenocarcinoma, High Grade PIN Prostate basal cells, proliferative cells, glandular epithelium Prostate epithelial cells Prostate secretory and ductal epithelium Reed-Sternberg cells, plasma cells Schwann cells, nerve processes, S100 +ve neoplasms Sex cord stromal tumours | In house documented procedures & manufacturer's instructions using Leica Biosystems Bond III Fully automated ICC and ISH stainer PR CA125 Cytokeratin, MNF116 Calcitonin NSE hCG CD138 (Syndecan-1) CD38 MIB-1 (Ki67)/p16 Racemase (P504s) P63 NXK3.1 Prostate-Specific-Antigen CD30 (Ki-1) S100 Inhibin, alpha |



9611
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

NHS Highland
Issue No: 004 Issue date: 08 September 2021

Testing performed at main address only

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|--|--|--|
| HUMAN BODY FLUIDS and TISSUES (cont'd) | <u>Immunocytochemistry of Histopathology examinations to assist in detection of clinical abnormalities</u> | In house documented procedures & manufacturer's instructions using |
| | Smooth muscle cells | Leica Biosystems Bond III Fully automated ICC and ISH stainer |
| | Smooth muscle cells, myoepithelial cells | Caldesmon |
| | Soft tissue neoplasms | SMA |
| | Squamous epithelial cells/Mesotheliomas | PACT |
| | Stratified squamous epithelium, basal cells and mesotheliomas | CK5 |
| | Striated and smooth muscle cells | Cytokeratin 5/6 |
| | T & B Lymphocytes, Leukaemias, acute lymphocytic lymphomas | Desmin |
| | T cell Lymphomas | TdT |
| | T cells | TIA-1 |
| | T cells | CD2 (LFA-2), CD3 |
| | T cells (helper & mature) | CD8 |
| | T cells, Natural killer cells, thymocytes | CD4 |
| | Thyroglobulin containing cells | CD7 |
| | Tissues of neuroendocrine origin | Thyroglobulin |
| | TTF-1 found in lung and thyroid (thyroid follicular cells) | Chromogranin A |
| | V.W. factor in endothelial cells | TTF-1 |
| | Urothelial cells/Breast | Factor XIIIa |
| | | GATA |



9611
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

NHS Highland
Issue No: 004 Issue date: 08 September 2021

Testing performed at main address only

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|---|--|---|
| HUMAN BODY FLUIDS and TISSUES (cont'd) | <u>Immunocytochemistry of Histopathology examinations to assist in detection of clinical abnormalities</u> | In house documented procedures & manufacturer's instructions using Leica Biosystems Bond III Fully automated ICC and ISH stainer CD117 (c-kit) |
| Paraffin sections of Skin and Oral biopsies | Various - mast cells, stem cells, Cajal cells, melanocytes, basal cells (skin) and mammary duct epithelium Various tumours Immunoglobulins and Complement | P16 Protein Leica Biosystems Bond III Fully automated ICC and ISH stainer |
| Frozen sections of Skin and Oral biopsies | <u>Morphological assessment and interpretation/diagnosis</u> <u>Immunofluorescence of Histopathology examinations to assist in detection of clinical abnormalities</u> IgA IgG C3 Comp <u>In Situ Hybridisation of Histopathology examinations to assist in detection of clinical abnormalities</u> | Microscopy SOP D-CLIN-001 & D-CLIN-002 In house documented procedures & manufacturer's instructions using Using antibodies to and microscopy;- Immunofluorescence;- documented procedure in S-ICC-008 & S-ICC-011 Leica Biosystems Bond III Fully automated ICC and ISH stainer EBERISH KAPPA ISH LAMBDA ISH Interpretation of staining pattern Microscopy SOP D-CLIN-001 & D-CLIN-002 |
| END | | |