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

University Hospitals Birmingham NHS Foundation Trust

Issue No: 002 Issue date: 10 August 2020

New Queen Elizabeth Contact: Helen Stokes
Hospital Birmingham Tel: +44 (0) 121 371 3344

Mindelsohn Way E-Mail: Helen.Stokes@uhb.nhs.uk

Website: https://www.uhb.nhs.uk/laboratory-

services-contact.htm

Testing performed at the above address only

Site activities performed away from the locations listed above:

Edgbaston

Birmingham

B15 2GW

| Location details | | Activity |
|---|----------------------------|--------------|
| Address Mortuary New Queen Elizabeth Hospital Birmingham Mindelsohn Way Edgbaston, Birmingham B15 2GW | Local Contact Helen Stokes | Body Storage |

Assessment Manager: DE Page 1 of 21



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

University Hospitals Birmingham NHS Foundation Trust

Issue No: 002 Issue date: 10 August 2020

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 TISSUE AND FLUIDS | Histology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis | Macroscopic and Microscopic examination: |
| Fresh Tissue | | In house documented frozen section procedure and manufacturer's instructions using Leica Cryostats CM1850 SOP: PDI_S020 |
| | | Specimen Dissection Manual Method using documented procedures SOP's PDI_S002 to PDI_S047 |
| | | Tissue Processing Documented procedures and manufacturer's instructions using Sakura Tissue- Tek VIP 6; Thermo Scientific Pathcentre and Excelsior (SOPs PDI_S016 and PDI_S033) |
| | | Tissue embedding In-house documentation and Manufactures instructions for the Thermo Shandon HistoStar embedding workstation (SOPs PGH_S029) |
| | | Tissue sectioning (Microtomy) Manual and semi-automated method using SOP PGH_S031 Leica Rotary Microtome's; PFM microtome's; Thermo Shandon (semi-automated) |
| | | Documented procedure and manufactures instructions for Leica XL Autostainer / Cover slipper (SOP PGH_S046) |
| | | Decalcification of tissue samples included in SOPs PDI_S013 and PID_S027 |

Assessment Manager: DE Page 2 of 21



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

University Hospitals Birmingham NHS Foundation Trust

Issue No: 002 Issue date: 10 August 2020

Testing performed at main address only

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|---|--|--|
| HUMAN BODY TISSUE AND FLUIDS (cont'd) | Histology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd) | Macroscopic and Microscopic examination: |
| Formalin fixed tissue processed to paraffin wax (FFPE) Fresh tissue Frozen Tissue | Tissue architecture and nuclear detail (Identification of basophilic and eosinophilic structures) | Routine Staining (H&E) using Leica XL Autostainer / Cover slipper (SOP PGH_S046) |
| 11025.11110000 | | Leica and Nikon Light Microscopes; Olympus; Zeiss (SOP PGH_S046) |
| Formalin fixed tissue processed to paraffin wax (FFPE) | Detection of the following: | In house documented procedures for Special Staining (manual): |
| | Amyloid | Congo (Stoke's) Red (PSS_S026) |
| | Elastin Fibres | Elastin van Gieson Stain (EVG) (PSS_S001) |
| | Collagen, connective tissue | Haematoxylin Van Gieson (HVG) (PSS_S005) |
| | Gram positive and Gram negative organisms | Gram Stain (PSS_S033) |
| | Fungi, Pneumocystis | Gram Twort Stain (PSS_S002) |
| | Haematopoietic Tissue | Grocott's Methanamine Silver (GMS) (PSS_S004) |
| | Fibrin | Long Giemsa (Wilkin's Method) Stain (PSS_S007) |
| | Collagen, connective tissue | Martius, Scarlet and Blue (MSB) (PSS_S035) |
| | Helicobacter-type organisms | Masson's Trichrome (PSS_S025) |
| | Helicobacter Pylori | Modified Giemsa PSS_S034 |
| | Mucin | Modified Masson's Fontana Stain (PSS_S010) |
| | | |

Assessment Manager: DE Page 3 of 21



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

University Hospitals Birmingham NHS Foundation Trust

Issue No: 002 Issue date: 10 August 2020

Testing performed at main address only

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|--|--|---|
| HUMAN BODY TISSUE AND FLUIDS (cont'd) | Histology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd) | Macroscopic and Microscopic examination: |
| Formalin fixed tissue processed to paraffin wax (FFPE) | Detection of the following: | In house documented procedures for Special Staining (manual): |
| | Mycobacterium Leprae | Mucicarmine (modified Southgate's) Stain (PSS_S013) |
| | Glomerular Basement Membranes | Modified ZN (Wade Fite) Stain (PSS_S012) |
| | Glycogen, neutral mucins, fungi, glomerular Basement Membranes | Periodic Acid Methenamine Silver (PAMS) Stain (PSS_S027) |
| | 2µm glomerular basement membranes | Periodic Acid Schiff's (PAS) 2μm PSS_S015 |
| | Copper associated protein, Hepatitis B Surface antigen | Rhodanine (PSS_S019) |
| | Calcium deposits | Shikata's Orcein (PSS_S014) |
| | Mast Cells | Toluidine Blue PSS_S021 |
| | Helicobacter-type organisms | Von Kossa Stain (PSS_S022) |
| | Basophilic and eosinophilic (H&E) Structures | Dako Cover Stainer SOP PGH_S053 |
| | | In- house documented immunohistochemical procedures and manufacturer's instructions using Dako Artisan autostainer SOP PSS_S049 |
| | Acid and Neutral mucins | Alcian Blue/ Periodic Acid Schiff's (ABPAS) |
| | Acid Mucins | Alcian Blue pH2.5 (AB) |
| | Amyloid | Congo Red |
| | Carbohydrates / Fungal Organisms / Alpha-1- antitrypsin | Daistase Periodic Acid Schiff's (PASD) |

Assessment Manager: DE Page 4 of 21



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

University Hospitals Birmingham NHS Foundation Trust

Issue No: 002 Issue date: 10 August 2020

Testing performed at main address only

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|--|--|--|
| HUMAN BODY TISSUE AND FLUIDS (cont'd) | Histology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd) | Macroscopic and Microscopic examination: |
| | | In- house documented immunohistochemical procedures and manufacturer's instructions using Dako Artisan autostainer SOP PSS_S049 |
| Formalin fixed tissue processed to paraffin wax (FFPE) | Fungal organisms | Grocott;s Methenamine Silver (GMS) |
| | Iron | Iron Stain |
| | Glomerular Basement Membranes | Jones' Methenamine Silver |
| | Connective Tissue | Masson's Trichrome |
| | Carbohydrates / Fungal Organisms / Glomerular Basement Membranes | Periodic Acid Schiff's (PAS) |
| | Reticulin fibres at 3µm and at 2µm | Reticulin-Nuclear Fast Red |
| | Spirochetes, Helicobacter pylori | Warthin Starry (WS) |
| | Acid Fast bacilli | Acid Fast Bacteria Stain (AFB) |
| | | In- house documented immunohistochemical procedures and manufacturer's instructions using DAKO Autostainer Link 48 Platforms (Dako Envision FLEX+ detection system) SOP PIC_S001 |
| | Alpha -1-Antitrypsin deposits | A1AT |
| | Adrenocorticotropin hormone expressing cells | Adrenocorticotropin hormone (ACTH) |
| | Smooth Muscle Cells. Myofibroblasts. Myoepithelial cells | Actin, smooth muscle |
| | Alpha- Synuclein Protein | Alpha-Synuclein |

Assessment Manager: DE Page 5 of 21



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

University Hospitals Birmingham NHS Foundation Trust

Issue No: 002 Issue date: 10 August 2020

Testing performed at main address only

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|--|--|---|
| HUMAN BODY TISSUE AND FLUIDS (cont'd) | Histology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd) | Macroscopic and Microscopic examination: |
| Formalin fixed tissue processed to paraffin wax (FFPE) | Detection of the following: | In- house documented immunohistochemical procedures and manufacturer's instructions using DAKO Autostainer Link 48 Platforms (Dako Envision FLEX+detection system) SOP PIC_S001 |
| | Alpha- 1- Fetoprotein expressing cells | Alpha- 1- Fetoprotein (AFP) |
| | Alpha-Methylacyl-CoA Racemase expressing cells | Alpha-Methylacyl-CoA |
| | Androgen Receptor expressing cells | Racemase(AMACR) |
| | T-cell, B-cells | Androgen Receptor |
| | B-cells | BCL2 Oncoprotein |
| | Beta-Amyloid pre-cursor protein | BCL6 Protein |
| | Beta-Catenin expressing cells | Beta-Amyloid (A4) |
| | B- Cells | Beta Catenin |
| | Epithelial Cells | BOB-1 |
| | Epithelial cells, Sialyl Lewisa containing glycolipids | CA-19.9 |
| | Calcitonin Expressing cells | Calcitonin |
| | Calponin expressing cells | Calponin |
| | Carcinoembryonic Antigen positive cells | Carcinoembryonic Antigen (CEA) |
| | | |

Assessment Manager: DE Page 6 of 21



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

University Hospitals Birmingham NHS Foundation Trust

Issue No: 002 Issue date: 10 August 2020

Testing performed at main address only

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|--|---|---|
| HUMAN BODY TISSUE AND FLUIDS (CONTD): | Histology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd): | Macroscopic and Microscopic examination: |
| Formalin fixed tissue processed to paraffin wax (FFPE) | Detection of the following: | In- house documented immunohistochemical procedures and manufacturer's instructions using DAKO Autostainer Link 48 Platforms (Dako Envision FLEX+detection system) SOP PIC_S001 |
| | Carcinoembryonic Antigen positive cells | Carcinoembryonic Antigen (CEA) (polyclonal) |
| | CD10 expressing tumours such as renal, liver, connective tissue | CD10 |
| | CD117 expressing cells. Mast Cells. Cajal Cells | CD117 |
| | CD123 expressing cells | CD123 |
| | B-cells. Plasma Cells | CD138 |
| | CD14 expressing cells | CD14 |
| | Hodgkin Cells. Reed-Sternberg Cells. | CD15 |
| | B-Cells | CD19 |
| | Lymphoblast. Langerhans Cells. Thymocytes | CD1a |
| | B-Cells | CD20cy |
| | Follicular Dendritic Cells, B-cells | CD21, CD23 |
| | T-Cells | CD3 |
| | CD30 positive carcinomas such as embryonal carcinoma | CD30 |
| | | |

Assessment Manager: DE Page 7 of 21



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

University Hospitals Birmingham NHS Foundation Trust

Issue No: 002 Issue date: 10 August 2020

Testing performed at main address only

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|--|---|---|
| HUMAN BODY TISSUE AND FLUIDS (CONTD): | Histology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd): | Macroscopic and Microscopic examination: |
| Formalin fixed tissue processed to paraffin wax (FFPE) | Detection of the following: | In- house documented immunohistochemical procedures and manufacturer's instructions using DAKO Autostainer Link 48 Platforms (Dako Envision FLEX+detection system) SOP PIC_S001 |
| | Vascular and Lymphatic Vessels. Cells of myeloid lineage | CD34 (Class II) |
| | T-Cells, B-Cells | CD43 |
| | Leucocytes | CD68 / KP1 CD68 / PG-M1 |
| | Macrophages. Monocytes T-Cells | CD7 CD79a |
| | B-Cells | CD8 |
| | T-Cells | CD99 |
| | CD99 expressing cells | CDX2 |
| | Epithelial Cells (colonic type) | Cytokeratin |
| | Epithelial Cells | Cytokeratin 19 |
| | Cytokeratin 19 expressing cells | CD7 |
| | Epithelial Cells (colonic type) | Cytokeratin 20 |
| | Basal cells such as prostate, breast. Tonsil epithelial cells. Squamous cells. Cytokeratin 5/6 expressing cells | Cytokeratin 5/6 |
| | Cytokeratin 7 expressing cells | Cytokeratin 7 |
| | Cytomegalovirus infected cells | Cytomegalovirus (CMV) |

Assessment Manager: DE Page 8 of 21



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

University Hospitals Birmingham NHS Foundation Trust

Issue No: 002 Issue date: 10 August 2020

Testing performed at main address only

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|--|---|---|
| HUMAN BODY TISSUE AND FLUIDS (CONTD): | Histology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd): | Macroscopic and Microscopic examination: |
| Formalin fixed tissue processed to paraffin wax (FFPE) | Detection of the following: | In- house documented immunohistochemical procedures and manufacturer's instructions using DAKO Autostainer Link 48 Platforms (Dako Envision FLEX+detection system) SOP PIC_S001 |
| | Smooth muscle cells. Striated muscle cells. Reactive mesothelial cells | Desmin |
| | TMEM16A Expressing cells | DOG1 (T-MEM) |
| | Dysferlin Protein | Dysferlin |
| | Epithelial Cells | E-Cadherin |
| | Epithelial Cells. Mesothelial Cells | Epithelial membrane antigen (EMA) |
| | Epstein-Barr virus latent membrane protein | Epstein-Barr virus infected cells |
| | Factor 13a expressing cells | (EBV) |
| | Follicular Stimulating Hormone expressing cells | Follicle stimulating Hormone (FSH) |
| | Astrocytes | Glial Fibrillary Acidic Protein (GFAP) |
| | Glutamine Synthetase expressing cells | Glutamine Synthetase |
| | Glypican-3 expressing cells | Glypican-3 |
| | Lymphocytes. NK cells. T-cells | Granzyme B |
| | Growth Hormone expressing cells | hGH |
| | Hairy Cell Leukemia | Hairy cell Leukemia |

Assessment Manager: DE Page 9 of 21



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

University Hospitals Birmingham NHS Foundation Trust

Issue No: 002 Issue date: 10 August 2020

Testing performed at main address only

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|--|---|---|
| HUMAN BODY TISSUE AND FLUIDS (CONTD): | Histology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd): | Macroscopic and Microscopic examination: |
| Formalin fixed tissue processed to paraffin wax (FFPE) | Detection of the following: | In- house documented immunohistochemical procedures and manufacturer's instructions using DAKO Autostainer Link 48 Platforms (Dako Envision FLEX+detection system) SOP PIC_S001 |
| | Hepatocyte Cells | Hepatocyte |
| | Herpes simplex virus infected cells. | HSV-1 |
| | Plasma Cells. Lymphoid cells containing IgG | IgG Gamma chains |
| | lg4 expressing cells | IgG4 |
| | Inhibin alpha expressing cells | Inhibin Alpha |
| | Proliferating cells | Ki67 |
| | Luteinizing Hormone expressing cells | Luteinizing Hormone (LH) |
| | Mast Cells | Mast Cell Tryptase |
| | Melan-A expressing cells | Melan A |
| | Melanocytes | Melanosome |
| | Merosin protein | Merosin Alpha |
| | Mesothelial Cells | Mesothelial Cell |
| | B-Cells. Plasma Cells. Reed- Sternberg cells | MUM1 |
| | MutL Protein Homlog1 Expressing cells | MLH1 |
| | | |

Assessment Manager: DE Page 10 of 21



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

University Hospitals Birmingham NHS Foundation Trust

Issue No: 002 Issue date: 10 August 2020

Testing performed at main address only

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|--|---|---|
| HUMAN BODY TISSUE AND FLUIDS (CONTD): | Histology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd): | Macroscopic and Microscopic examination: |
| Formalin fixed tissue processed to paraffin wax (FFPE) | Detection of the following: | In- house documented immunohistochemical procedures and manufacturer's instructions using DAKO Autostainer Link 48 Platforms (Dako Envision FLEX+detection system) SOP PIC_S001 |
| | MutL Protein Homlog2 Expressing cells | MSHS2 |
| | MutL Protein Homlog6 Expressing Cells | MSH6 |
| | Myelin PLP protein | Myelin PLP |
| | Neurones | Neu N |
| | Neurones. Axonal processes | Neurofilament Protein |
| | OCT3/4 expressing cells Assessment of Oestrogen | Octamer/binding Transcription factor 3 /4 (OCT3/4) |
| | receptor status | Oestrogen receptor (ER) Alpha |
| | P53 protein | P53 |
| | P62 Protein | P62 |
| | B-Cells | PAX5 |
| | Placental Alkaline Phosphatase (PLAP) Expressing cells | Placental Alkaline Phosphatase (PLAP) |
| | Lymphatic invasion. Cajal Cells. Lymphatic epithelial cells | Podoplanin |
| | Postmeiotic segregation Increased 2 expressing cells | Postmeiotic segregation Increased 2 (PMS2) |

Assessment Manager: DE Page 11 of 21



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

University Hospitals Birmingham NHS Foundation Trust

Issue No: 002 Issue date: 10 August 2020

Testing performed at main address only

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|--|---|---|
| HUMAN BODY TISSUE AND FLUIDS (CONTD): | Histology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd): | Macroscopic and Microscopic examination: |
| Formalin fixed tissue processed to paraffin wax (FFPE) | Detection of the following: | In- house documented immunohistochemical procedures and manufacturer's instructions using DAKO Autostainer Link 48 Platforms (Dako Envision FLEX+detection system) SOP PIC_S001 |
| | Assessment of progesterone receptor status. Meningioma Cell | Progestrone receptor (PGR) |
| | Prolactin expressing cells | Prolactin |
| | Prostate luminal epithelial cells. | PSA |
| | S100 protein expressing cells | S100 |
| | SDHA expressing cells | SDHA |
| | SDHB expressing cells | SDHB |
| | Alpha-Sarcoglycan Staining protein | Alpha- Sarcoglycan Staining |
| | Spectrin expressing cells. Erythrocytes | Spectrin |
| | Neuroendocrine Cells. | Synatophysin |
| | Thymocytes | Terminal Deoxynucleotidyl Transferase (TdT) |
| | Thyroglobulin expressing cells | Thyroglobulin |
| | Thyroid Stimulating hormone expressing cells | Thyroid Stimulating hormone (TSH) |
| | Mesenchymal Cells | Vimentin |
| | Wilms' Tumour 1 Protein (WT1) expressing cells. | WT1 |
| | | |

Assessment Manager: DE Page 12 of 21



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

University Hospitals Birmingham NHS Foundation Trust

Issue No: 002 Issue date: 10 August 2020

Testing performed at main address only

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|--|---|---|
| HUMAN BODY TISSUE AND FLUIDS (CONTD): | Histology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd): | Macroscopic and Microscopic examination: |
| Formalin fixed tissue processed to paraffin wax (FFPE) | Detection of the following: | In- house documented immunohistochemical procedures and manufacturer's instructions using Dako Omnis immunostainer SOP PIC_S053, DAKO Autostainer Link 48 Platforms (Dako Envision FLEX+ detection system) SOP PIC_S001 |
| | AE1/ AE3- Epithelial Tumours cells | AE1/ AE3 |
| | Alpha-1-antitryspin- expressing cells (A1A) | Alpha-1-antitryspin- expressing cells (A1A) |
| | Beta- catenin expressing cells | Beta-catenin |
| | BCL2 Oncoprotein expressing cells | BCL2 |
| | Large B-cell lymphoma/ Follicular lymphoma / Burkitts Lymphoma | BCL6 |
| | Epithelial tissue | Broad Spectrum Cytokeratin (MNF116) |
| | BSAP expressing B-Cells | BSAP |
| | CA19.9 expressing cells | CA19.9 |
| | CA 125 expressing cells | CA125 |
| | Calponin Expressing cells | Calponin |
| | Prostate Basal Cells / tonsil epithelial cells / Squamous cell carcinoma (Lung) | CK5 |
| | Glandular epithelial cells / transitional epithelial cells | CK7 |
| | Cytokeratin 8 expressing cells | CK8 |
| | Cytokeratin 8/18 expressing cells | CK8/18 |
| | Cytokeratin 20 | Cytokeratin 20 |

Assessment Manager: DE Page 13 of 21



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

University Hospitals Birmingham NHS Foundation Trust

Issue No: 002 Issue date: 10 August 2020

Testing performed at main address only

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|--|---|---|
| HUMAN BODY TISSUE AND FLUIDS (CONTD): | Histology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd): | Macroscopic and Microscopic examination: |
| Formalin fixed tissue processed to paraffin wax (FFPE) | Detection of the following: | In- house documented immunohistochemical procedures and manufacturer's instructions using Dako Omnis immunostainer SOP PIC_S053 |
| | Basal Cells / Squamous epithelium | High Molecular Weight Cytokeratin (34BE12) |
| | CD1a expressing cells | CD1a |
| | CD123 expressing Cells | CD123 |
| | CD3- T-Cells | CD3 |
| | CD4 T-cells | CD4 |
| | CD5 expressing cells | CD5 |
| | CD7- T Cells | CD7 |
| | CD8 Expressing cells | CD8 |
| | CD14 expressing cells | CD14 |
| | CD15 – mature granulocytes / mononuclear Hodgkin's cells / Reed-Sternberg cells | CD15 |
| | CD19 expressing B Cells | CD19 |
| | CD20 - B cells | CD20 |
| | CD21- Follicular dendritic cells / B-cells | CD21 |
| | CD23 expressing cells | CD23 |
| | CD30 expressing cells | CD30 |
| | CD31- Endothelial cells | CD31 |

Assessment Manager: DE Page 14 of 21



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

University Hospitals Birmingham NHS Foundation Trust

Issue No: 002 Issue date: 10 August 2020

Testing performed at main address only

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|--|---|---|
| HUMAN BODY TISSUE AND FLUIDS (CONTD): | Histology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd): | Macroscopic and Microscopic examination: |
| Formalin fixed tissue processed to paraffin wax (FFPE) | Detection of the following: | In- house documented immunohistochemical procedures and manufacturer's instructions using Dako Omnis immunostainer SOP PIC_S053 |
| | CD34 - Vascular and lymphatic tumours | CD34 |
| | CD43 – T Cells | CD43 |
| | CD45- Cells of lymphoid origin | CD45 (LCA) |
| | CD56- Natural Killer Cells / NK-like T Cells | CD56 |
| | CD57 Expressing cells | CD57 |
| | CD68 KP1- Macrophages and Monocytes | CD68 KP1 |
| | Macrophages | CD68 PGM1 |
| | B-cells | CD79a |
| | CD117 expressing cells | CD117 |
| | Multiple Myeloma | CD138 |
| | Adenocarcinomas / Carcinoids in GI tract | CD-X2 |
| | Neuroendocrine cells | Chromogranin A |
| | Cyclin D1 expressing cells | Cyclin D1 |
| | CMV infected cells | Cytomegalovirus |
| | Smooth and striated muscle cells | Desmin |
| | TMEM16A expressing cells | DOG-1 |
| | Epithelial cells | E-Cadherin |

Assessment Manager: DE Page 15 of 21



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

University Hospitals Birmingham NHS Foundation Trust

Issue No: 002 Issue date: 10 August 2020

Testing performed at main address only

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|--|---|---|
| HUMAN BODY TISSUE AND FLUIDS (CONTD): | Histology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd): | Macroscopic and Microscopic examination: |
| Formalin fixed tissue processed to paraffin wax (FFPE) | Detection of the following: | In- house documented immunohistochemical procedures and manufacturer's instructions using Dako Omnis immunostainer SOP PIC_S053 |
| | Epithelial Cells | EP4 |
| | Epithelial membrane antigen expressing cells | Epithelial membrane Antigen (EMA) |
| | Epithelial tumour markers (AE1/AE3) | Epithelial tumour markers (AE1/AE3) |
| | Epithelial antigen | Epithelial Related antigen (ESA) |
| | Epstein-Barr virus infected cells | Epstein -Barr Virus (EBV) |
| | Follicular Stimulating Hormone expressing Cells | FSH |
| | Growth Hormone Expressing Cells | Growth Hormone |
| | Astrocytes | Glial Fibrillary Acidic Protein (GFAP) |
| | Glypican 3 expressing cells | Glypican-3 |
| | Hepatitis B virus surface antigen | HBsAG |
| | Human Herpes virus (Type 8) latent nuclear antigen | HHV-8 CM |
| | Herpes Simplex Virus -1 infected cells | HSV-1 |
| | IDH (Isocitrate dehydrogenase) 1 | IDH1 |
| | IgG4 Expressing Cells | IgG4 |
| | Insulin expressing cells | Insulin |
| | Ki-67 expressing cells | Ki67 |

Assessment Manager: DE Page 16 of 21



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

University Hospitals Birmingham NHS Foundation Trust

Issue No: 002 Issue date: 10 August 2020

Testing performed at main address only

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|--|---|---|
| HUMAN BODY TISSUE AND FLUIDS (CONTD): | Histology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd): | Macroscopic and Microscopic examination: |
| Formalin fixed tissue processed to paraffin wax (FFPE) | Detection of the following: | In- house documented immunohistochemical procedures and manufacturer's instructions using Dako Omnis immunostainer SOP PIC_S053 |
| | Leutenizing Hormone | Leutenizing Hormone (LH) |
| | Melan- A expressing cells | Melan-A |
| | Melanocytes | Melanosome |
| | Mucin 1 expressing cells (CD227) | MUC1 |
| | MUM-1- B Cells in the light zone of the germinal centre/ plasma cells / activated T-Cells | MUM-1 |
| | Myeloperoxidase Expressing cells | Myeloperoxidase |
| | Neurofilament Protein – expressing cells | Neurofilament Protein |
| | Neuronal cell | Neu-N |
| | Oestrogen Receptor status | Oestrogen Receptor |
| | P16 expressing cells | P16 |
| | P53 Protein | P53 |
| | Pax-8 expressing cells | Pax-8 |
| | Podoplanin expressing cells | Podoplanin (D2-40) |
| | Progesterone Receptor | Progesterone Receptor |
| | Prolactin expressing cells | Prolactin |
| | Prostate Specific antigen expressing cells | Prostatic specific antigen (PSA) |

Assessment Manager: DE Page 17 of 21



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

University Hospitals Birmingham NHS Foundation Trust

Issue No: 002 Issue date: 10 August 2020

Testing performed at main address only

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|--|---|---|
| HUMAN BODY TISSUE AND FLUIDS (CONTD): | Histology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd): | Macroscopic and Microscopic examination: |
| Formalin fixed tissue processed to paraffin wax (FFPE) | Detection of the following: | In- house documented immunohistochemical procedures and manufacturer's instructions using Dako Omnis immunostainer SOP PIC_S053 |
| | Carcinoma of Prostate | Prostatic Acid Phosphatase (PSAP) |
| | S100 expressing cells | S100 |
| | Smooth Muscle cells / Myofibroblasts / Myoepithelial cells | Smooth Muscle Actin (SMA) |
| | Smooth Muscle myosin / Myoepitheial cells | Smooth Muscle Myosin (SMMYO) |
| | Synaptophysin expressing cells | Synaptophysin |
| | Thyroid Stimulating hormone expressing cells | TSH |
| | Thyroid Transcription Factor -1 expressing cells | TTF1 |
| Slides Prepared in house as above | Morphological Assessment and interpretation / Diagnosis | PAA_S018. |
| Fresh tissue | | Preparation and processing of specimens for electron microscopy using Leica EMTP Tissue Processor (SOP range PEM_S056 to PEM_S057; PEM_S063 to PEM_S072) |
| | | Sectioning samples Semi-thin and ultrathin sections Leica Ultra cut UC7RT Ultra microtome (SOP PEM_S058; PEM_S072 to PEM_S077) |

Assessment Manager: DE Page 18 of 21



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

University Hospitals Birmingham NHS Foundation Trust

Issue No: 002 Issue date: 10 August 2020

Testing performed at main address only

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|---|--|---|
| HUMAN BODY TISSUE AND FLUIDS (CONTD): | Histology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd): | Macroscopic and Microscopic examination: |
| | | in-house documented procedures based on Electron Microscope equipment manuals and standard methods as specified below. |
| Glutareldehyde Fixed Resin Embedded Tissue sections on glass slides prepared as above | | Staining of electron microscope tissue sections: Toluidine Blue Staining Thionin Staining Uranyl Acetate Staining Lead Citrate Staining (SOP: PEM_S058) |
| | Ultrastructural Examination and digital electron micrographs Semithin and Ultrathin sections to identify and exclude ultrastructural morphological abnormalities for the purpose of diagnosis. | Light Microscope and FEI Technai G2 electron microscope (SOP PEM_S025 and PEM_S035) |
| | Neuropathology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis: | |
| Fresh Tissue: Muscle | | Receipt and preparation of the muscle tissue (SOP PMU_S058) |
| | | Preparation and muscle tissue frozen sectioning using the Leica CM1850 UV Cryostat (SOP: PMU_S001) |
| Fresh Frozen Tissue: Muscle | Mitochondrial Complexes | Cytochrome C Oxidase staining PMU_S010 |
| | Mitochondrial Complexes | Gomori Trichrome staining PMU_S005 |
| | Basophilic and eosinophilic structures | Haematoxylin and Eosin staining PMU_S004 |

Assessment Manager: DE Page 19 of 21



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

University Hospitals Birmingham NHS Foundation Trust

Issue No: 002 Issue date: 10 August 2020

Testing performed at main address only

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|---|---|---|
| HUMAN BODY TISSUE AND FLUIDS (CONTD): | Neuropathology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis: | Preparation and muscle tissue frozen sectioning using the Leica CM1850 UV Cryostat (SOP: PMU_S001) |
| Fresh Frozen Tissue: Muscle | Demonstration of Lipofushin | Muscle Acid Phosphatase staining PMU_S013 |
| | Demonstration of Lipofushin MHC | Myosin Adenosine Triphosphatase Staining pH 9.4 & pH 4.6 PMU_S012 Major Histocompatibility Complex |
| | | PMU_S055 |
| | NADH | NADH Staining PMU_S009 |
| Fresh Frozen Tissue: Muscle | PAS +ve substances | Periodic Acid – Schiffs (PAS) Staining PMU_S007 |
| | Phosphorylase activity | Phosphorylas staining |
| | SDH activity | Succinate Dehydrogenase staining |
| | Lipids | Sudan Black staining |
| Neuropathological tissue: Formalin fixed tissue processed to paraffin wax (FFPE) Fresh tissue Frozen Tissue | | In- house documented immunohistochemistry procedures and manufacturer's instructions using DAKO Autostainer Link 48 Platforms (Dako Envision FLEX+ detection system) SOP PIC_S001 |
| | Dystrophin (C-terminus) protein | Dystrophin (C-terminus) |
| | Dystrophin (Rod Zone) protein | Dystrophin (Rod Zone) |
| | Emerin Protein | Emerin |
| | Skeletal Muscle fast fibres | MHCf |
| | Skeletal muscle slow fibres | MHCs |
| | Myoepithelial Cells. Smooth muscle cells. | Myosin Heavy Chain/ smooth muscle |

Assessment Manager: DE Page 20 of 21



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

University Hospitals Birmingham NHS Foundation Trust

Issue No: 002 Issue date: 10 August 2020

Testing performed at main address only

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|--|---|--|
| HUMAN BODY TISSUE AND FLUIDS (CONTD): | Neuropathology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis: | |
| Slides Prepared in house as above | Morphological Assessment and interpretation / Diagnosis | PAA_S018 |
| | Diagnostic Cytology Examination to assist in clinical Investigation | Macroscopic and Microscopic examination: |
| | Preparation and examination of cellular material to identify or exclude cytological abnormalities | In house documentation procedure and manufacturer's instructions using the following equipment. SOP Range PCY_S001 to PCY_S035 |
| Air Dried Preparations. Body fluids, CSFs | | Rotina Centrifuge Shandon Cytospin 4 |
| Wet fixed Preparations. Body fluids, urine, CSFs, aspirates, washings, brushings, EBUS | | Processing and staining using Papanicolaou, modified Giemsa and H&E |
| FNA Air Dried Preparations: breast, thyroid, lymph node | Cellularity assessment | Thermos Scientific Linistain staining machine |
| Slides Prepared in house as above | Morphological Assessment and interpretation / Diagnosis | PAA_S018 |
| END | | |

Assessment Manager: DE Page 21 of 21