


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>UKAS</b> MEDICAL</p> <p>8191</p> <p>Accredited to ISO 15189:2012</p>	<p><b>North Bristol NHS Trust</b></p> <p>Issue No: 001    Issue date: 22 June 2017</p>	
	<p>Department of Neuropathology Pathology Science Building (Phase II) Southmead Hospital Bristol BS10 5NB</p>	<p>Contact: Catherine Rowe Tel: +44 (0)1179 505 050 E-Mail: catherine.rowe@nbt.nhs.uk Website: www.nbt.nhs.uk</p>
<p><b>Testing performed at the above address only</b></p>		

### DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p><b>HUMAN BODY TISSUE AND FLUIDS</b></p> <p>Tissue samples, predominantly from the central nervous system,. (Excludes any CNS samples taken for forensic examination)</p>	<p><u>Neuropathology examinations to assist in clinical investigations</u></p>	<p>Documented in house procedures in conjunction with manufacturer's instructions for:</p> <p>Dissection NP-LAB-SOP-003</p> <p>Decalcification NP-LAB-SOP-003</p> <p>Tissue Processing Thermo Scientific Excelsior AS (biopsy processing) Thermo Scientific Excelsior ES (Post mortem processing) in conjunction with in house documented methods: NP-LAB-SOP-004</p> <p>Embedding Embedding centre TES99 Medite medizintechnik</p> <p>Microtomy Rotary Microtome – Leica RM2235 and Base Sledge Microtome – Leica SM2400 NP-LAB-SOP-005</p>



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Neuropathology examinations to assist in clinical investigations</u> (cont'd)	Documented in house procedures in conjunction with manufacturer's instructions for:
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides	Special tinctorial staining for the demonstration of:	Histochemical Staining using Manual Techniques
	Basophilic and eosinophilic structure	Haematoxylin and Eosin NP-LAB-SOP-042
	Collagen	Haematoxylin Van Gieson NP-LAB-SOP-047
	Connective tissue (reticulin fibres)	Reticulin stain NP-LAB-SOP-044
	Mucopolysaccharides and elastic fibres	Alcian Blue Verhoef's Van Gieson NP-LAB-SOP-063
	Mucins – acid and neutral	Alcian Blue/PAS NP-LAB-SOP-033
	Elastic fibres and mast cell granules	Elastic Van Gieson NP-LAB-SOP-046
	Neurofibrillary tangles and plaques	Gallyas method for neurofibrillary changes NP-LAB-SOP-055
	Gram positive and Gram negative organisms	Gram Twort NP-LAB-SOP-036
	Myelin, nissl substance, glial cells	Luxol fast blue/Cresyl violet NP-LAB-SOP-037
	Melanin	Masson Fontana NP-LAB-SOP-056
	Muscle, bone, hyaline casts, erythrocytes, fibrin, collagen	Mauritius Scarlet Blue NP-LAB-SOP-038
	Muscle, rbc, fibrin, collagen	Masson Trichrome NP-LAB-SOP-051
Acidophils, basophils, chromophobes	Orange Fuchsin Green NP-LAB-SOP-052	



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides (cont'd)</p> <p>Tissue samples, predominantly from the central nervous system on FFPE slides (Formalin fixed paraffin embedded)</p>	<p><u>Neuropathology examinations to assist in clinical investigations</u> (cont'd)</p> <p>Special tinctorial staining for the demonstration of:</p> <p>Nerve fibres</p> <p>Fungi, some bacteria, cerebrosides and sphingomyelin, sialomucins and neutral mucins, glycogen, starch, elastin, reticulin, some lipofuscins</p> <p>Ferric iron</p> <p>Astrocytes, myelin, collagen, reticulin</p> <p>Myelin sheaths</p> <p>Amyloid, elastic fibres</p> <p>Fungi</p> <p>Acid fast bacilli</p> <p>Immunohistochemistry of Histopathology samples of neurological origin to demonstrate the following:</p> <p>Corticotrophs in adenohypophysis</p> <p>Lewy Body and Neuropil Marker.</p>	<p>Documented in house procedures in conjunction with manufacturer's instructions for:</p> <p>Histochemical Staining using Manual Techniques</p> <p>Palmgren's method NP-LAB-SOP-053</p> <p>Periodic Acid Schiff and Periodic Acid Schiff/Diastase NP-LAB-SOP-035 &amp; NP-LAB-SOP-034</p> <p>Perl's Prussian blue NP-LAB-SOP-039</p> <p>Phosphotungstic acid haematoxylin (PTAH) NP-LAB-SOP-048</p> <p>Solochrome Cyanine NP-LAB-SOP-040</p> <p>Sirius Red NP-LAB-SOP-049</p> <p>Tome method NP-LAB-SOP-045</p> <p>Ziehl-Neelsen (ZN) NP-LAB-SOP-041</p> <p>Documented in house procedures in conjunction with manufacturer's instructions for: Immunocytochemistry Automated using Ventana Benchmark Ultra NP-LAB-SOP-007 incorporating the following antibodies:</p> <p>Adrenocorticotrophic Hormone</p> <p>Alpha synuclein</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Tissue samples, predominantly from the central nervous system on FFPE slides (Formalin fixed paraffin embedded) (cont'd)</p>	<p><u>Neuropathology examinations to assist in clinical investigations</u> (cont'd)</p> <p>Immunohistochemistry of Histopathology samples of neurological origin to demonstrate the following:</p> <p>AT8 Clone of TAU</p> <p>Anaplastic oligo and anaplastic astrocytomas</p> <p>Atypical teratoid/rhabdoid tumours.</p> <p>10 amino acid sequence from amyloid beta protein.</p> <p>Labels senile plaques, extraneuronal tangles</p> <p>Marker for Adamantinomatous craniopharyngioma</p> <p>Reacts with cytokeratin 52 kDa (Moll #8) &amp; weakly with cytokeratin 43 kDa (Moll #7). Not Moll #18</p> <p>T cells</p> <p>Plasma cells</p> <p>B-Cell Marker</p> <p>Endothelial cell marker.</p> <p>Endothelial cells of blood vessels.</p> <p>Germinoma marker</p> <p>Pan T/B cell marker</p> <p>Monocytes and macrophages</p> <p>Neuroendocrine marker for tumours</p> <p>54kD cytokeratin.</p>	<p>Documented in house procedures in conjunction with manufacturer's instructions for:</p> <p>Immunocytochemistry Automated using Ventana Benchmark Ultra NP-LAB-SOP-007 incorporating the following antibodies:</p> <p>AT8(PHF-TAU AT8)</p> <p>ATRX</p> <p>BAF 47</p> <p>Beta amyloid protein 4G8</p> <p>Beta amyloid precursor protein</p> <p>Beta Catenin</p> <p>CAM 5.2</p> <p>CD3</p> <p>CD138</p> <p>CD20 (L26)</p> <p>CD31</p> <p>CD34 (endothelial cell)</p> <p>CD117</p> <p>CD45 (Leucocyte common ab)</p> <p>CD68 (macrophage KP1)</p> <p>Chromogranin A</p> <p>Cytokeratin 7</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Tissue samples, predominantly from the central nervous system on FFPE slides (Formalin fixed paraffin embedded) (cont'd)</p>	<p><u>Neuropathology examinations to assist in clinical investigations</u> (cont'd)</p> <p>Immunohistochemistry of Histopathology samples of neurological origin to demonstrate the following:</p> <p>46kD intermediate filament protein.</p> <p>Rhabdomyosarcoma, leiomyoma, leiomyosarcoma and mesotheliomas. Desminopathies in muscle</p> <p>Epithelia marker (secretory). Clone E29</p> <p>Anti-human epidermal growth factor receptor ab clone H9B4</p> <p>Beta sub-unit of FSH,</p> <p>Astrocytes and some ependymal cells</p> <p>Somatotroph cells</p> <p>Histone H3 with K27M mutation</p> <p>Melanosome/Melanoma</p> <p>Herpes Simplex Virus 1</p> <p>Herpes Simplex Virus 2</p> <p>Placenta trophoblasts, hydatiform mole, choriocarcinoma.</p> <p>Astrocytoma and oligodendroglioma tumour cell marker</p> <p>Cytokeratin proteins 5, 6 and 18</p> <p>Lamda +ve plasma cells</p> <p>Gonadotrophic cells of pituitary</p>	<p>Documented in house procedures in conjunction with manufacturer's instructions for: Immunocytochemistry Automated using Ventana Benchmark Ultra NP-LAB-SOP-007 incorporating the following antibodies:</p> <p>Cytokeratin 20</p> <p>Desmin</p> <p>Epithelial membrane antigen</p> <p>Human EGFR pan</p> <p>Follicle stimulating hormone</p> <p>Glial fibrillary acidic protein</p> <p>Growth hormone</p> <p>Histone H3, K27M mutant</p> <p>HMB45 (melanoma)</p> <p>Herpes Simplex Virus 1</p> <p>Herpes Simplex Virus 2</p> <p>Human chorionic gonadotrophin</p> <p>IDH1 R132H</p> <p>LP34</p> <p>Lamda light chains</p> <p>Luteinising hormone</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Tissue samples, predominantly from the central nervous system on FFPE slides (Formalin fixed paraffin embedded) (cont'd)</p> <p>Cerebrospinal Fluid fixed on glass slides</p>	<p><u>Neuropathology examinations to assist in clinical investigations</u> (cont'd)</p> <p>Immunohistochemistry of Histopathology samples of neurological origin to demonstrate the following:</p> <p>Ubiquitin-positive and tau-negative inclusions</p> <p>Beta sub-unit of TSH &amp; thyrotropic cells</p> <p>Toxoplasma Gondii</p> <p>Mesenchymal origin.</p> <p>Varicellar Zoster Virus</p> <p>Cytological investigation of Cerebrospinal Fluid (CSF) to detect cellular abnormalities to assist in clinical investigations</p> <p>Detection of:</p> <p>Reacts with cytokeratin 52 kDa (Moll #8) &amp; weakly with cytokeratin 43 kDa (Moll #7). Not Moll #18</p> <p>Plasma cells</p>	<p>Documented in house procedures in conjunction with manufacturer's instructions for: Immunocytochemistry Automated using Ventana Benchmark Ultra NP-LAB-SOP-007 incorporating the following antibodies:</p> <p>TDP-53</p> <p>Thyroid stimulating hormone</p> <p>Toxoplasma Gondii</p> <p>Vimentin</p> <p>Varicella Zoster Virus</p> <p>Documented in house procedures in conjunction with manufacturer's instructions for: Specimen Preparation NP/LAB/SOP/011 Cantel Medical SP Class I Thermo Scientific Cytospin 4 Staining NP/LAB/SOP/011</p> <p>Microscope – Nikon Y-THS</p> <p>Manual Immunohistochemistry using Vectastain Elite ABC and Biogenex Polymer HRP NP-LAB-SOP-007 NP-LAB-MET-010 NP-LAB-MET-015</p> <p>Incorporating the following antibodies:</p> <p>CAM 5.2</p> <p>CD138</p>



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HUMAN BODY TISSUE AND FLUIDS (cont'd)  Cerebrospinal Fluid fixed on glass slides (cont'd)	<u>Neuropathology examinations to assist in clinical investigations</u> (cont'd)  Cytological investigation of Cerebrospinal Fluid (CSF) to detect cellular abnormalities to assist in clinical investigations (cont'd)  Detection of: (cont'd)  B-Cell marker  Endothelial cells of blood vessels.  Pan T/B cell marker  Monocytes and macrophages  Epithelia marker (secretory) Clone E29  Astrocytes and some ependymal cells  Melanosome/melanoma  Proliferating cells  Glial & epenymal cells, & Schwann cells of PNS  T cell marker	Documented in house procedures in conjunction with manufacturer's instructions for: Specimen Preparation NP/LAB/SOP/011 Cantel Medical SP Class I Thermo Scientific Cytospin 4 Staining NP/LAB/SOP/011  Microscope – Nikon Y-THS  Manual Immunohistochemistry using Vectastain Elite ABC and Biogenex Polymer HRP NP-LAB-SOP-007 NP-LAB-MET-010 NP-LAB-MET-015  Incorporating the following antibodies:  CD20 (L26)  CD34 (endothelial cell)  CD45 (leucocyte common ab)  CD68 (macrophage KP1)  Epithelial Membrane Antigen  Glial Fibrillary Acidic Protein  HMB45 (melanoma)  MIB1 (Ki-67)  S100  UCLH1





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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Muscle biopsy on FFPE slides (Formalin fixed paraffin embedded)</p>	<p><u>Neuropathology examinations to assist in clinical investigations</u> (cont'd)</p> <p>Histological examination of muscle and nerve biopsy material to assist in clinical investigations</p> <p>Demonstration of:</p> <p>Basophilic and eosinophilic structures</p> <p>Collagen</p> <p>Amyloid, elastic fibres</p>	<p>Documented in house procedures in conjunction with manufacturer's instructions for: Specimen Preparation NP-LAB-SOP-013</p> <p>Tissue Processing: Thermo Scientific Excelsior AS (biopsy processing) Thermo Scientific Excelsior ES (Post mortem processing) NP-LAB-SOP-004 Embedding: Embedding centre TES99 Medite medizintechnik</p> <p>Microtomy: Rotary Microtome – Leica RM2235 Base Sledge Microtome – Leica SM2400 NP-LAB-SOP-005</p> <p>Histochemical Staining using Manual Techniques</p> <p>Haematoxylin and Eosin NP-LAB-SOP-042</p> <p>Haematoxylin Van Gieson NP-LAB-SOP-047</p> <p>Sirius Red NP-LAB-SOP-049</p> <p>Immunocytochemistry</p> <p>Automated using Ventana Benchmark Ultra NP-LAB-SOP-007</p> <p>Clinical interpretation of stained slide: NP/MGT/SOP/004 NP/MGT/SOP/005 NP/MGT/SOP/007</p>



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Muscle biopsy	Examination of frozen tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Specimen Preparation NP-LAB-SOP-013
	Demonstration of:	Cryotomy NP-LAB-SOP-012
	Lysosomes	Cryostat – Leica CM3050S
	ATPase activity	Histochemical Staining Using Manual Techniques
	Cytochrome Oxidase activity	Acid Phosphatase Naphthol AS-BI Phosphate NP-LAB-MET-055
	Mitochondrial myopathy	ATPase NP-LAB-MET-061
	Mitochondria/ Ragged Red Fibres	Cytochrome Oxidase activity NP-LAB-MET-062
	Basophilic and eosinophilic structures	Cytochrome Oxidase/ Succinic Dehydrogenase NP-LAB-MET-063
	Collagen	Gomori Trichrome NP-LAB-MET-068
	ATPase activity	Haematoxylin and Eosin NP-LAB-MET-016
	Myodenylate Deaminase activity	Haematoxylin Van Gieson NP-LAB-MET-065
	NADH-Tetrazolium activity	Metachromatic ATPase NP-LAB-MET-071
		Myodenylate Deaminase NP-LAB-MET-058
		NADH-Tetrazolium Reductase NP-LAB-MET-074



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Neuropathology examinations to assist in clinical investigations</u> (cont'd)	In house documented methods and manufacturer's instructions
Muscle biopsy (cont'd)	Demonstration of: (cont'd)	Histochemical Staining Using Manual Techniques (cont'd)
	Lipids	Oil Red O NP-LAB-MET-075
	Glycogen	Periodic Acid Schiffs & Periodic Acid Schiffs/ Diastase NP-LAB-MET-078/64
	Phosphofructokinase activity	Phosphofructokinase NP-LAB-MET-091
	Phosphorylase activity	Phosphorylase NP-LAB-MET-080
	SDH activity	Succinic Dehydrogenase NP-LAB-MET-083
Muscle biopsy	Immunohistochemistry of histopathology samples of neurological origin to detect the following:	Manual immunohistochemistry using Vectastain Elite ABC and Biogenex Polymer HRP methods  NP-LAB-SOP-007 NP-LAB-MET-010 NP-LAB-MET-015 Incorporating the following antibodies:
	Dystrophin associated glycoprotein	Alpha Dystroglycan
	Dystrophin	Beta Dystroglycan
	Inflammation in muscle	Beta 2 Microglobulin
	Neoepitope on poly C9 complement factor	C5b-9
	Membrane staining of muscle fibres.	Caveolin-3
	Plasma cells	CD138
	B-cell marker	CD20 (L26)



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Neuropathology examinations to assist in clinical investigations</u> (cont'd)	In house documented methods and manufacturer's instructions
Muscle biopsy (cont'd)	Immunohistochemistry of histopathology samples of neurological origin to detect the following: (cont'd)	Manual immunohistochemistry (cont'd)
	Endothelial cells of blood vessels.	CD34 (endothelial cell)
	Pan T/B cell marker	CD45 (leucocyte common ab)
	Monocytes and macrophages	CD68 (macrophage KP1)
	Smooth and striated muscle cells, mesothelial cells. Identification of desminomas, rhabdomyosarcomas, leiomyomas, and mesotheliomas.	Desmin
	Deficiency is associated with LMD 2B & Myoshi Myopathy	Dysferlin (Hamlet)
	Dystrophin in muscle fibre membranes	Dystrophin 1 (rod domain)
	Dystrophin in muscle fibre membranes	Dystrophin 2 (C terminus)
	Dystrophin in muscle fibre membranes	Dystrophin 3 (N or Amino terminus)
	X-linked emery	Emerin
	Reacts with the 300kD	Merosin (laminin alpha 2 chain)
	Labels proliferating cells	MIB1 (Ki67)
	For type II muscle fibres	Myosin fast
	For type I muscle fibres	Myosin slow
	Alpha-actin and filaments. Myotilinopathy.	Myotilin
	Antibody to phosphorylated and unphosphorylated neurofilament	Neurofilament (pan)



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Muscle biopsy (cont'd)</p>	<p><u>Neuropathology examinations to assist in clinical investigations</u> (cont'd)</p> <p>Immunohistochemistry of histopathology samples of neurological origin to detect the following: (cont'd)</p> <p>200 &amp; 70 KDA (phosphorylated)</p> <p>Membrane staining in normal muscle.</p> <p>Multimeric signal protein</p> <p>Adhalin</p> <p>Gamma-Sarcoglycanopathy (LGMD2C)</p> <p>Membrane integrity</p> <p>T-cell marker</p> <p>Dystrophin related protein (DRP).</p>	<p>In house documented methods and manufacturer's instructions</p> <p>Manual immunohistochemistry (cont'd)</p> <p>Neurofilament (phosphorylated)</p> <p>Nitric Oxide Synthase-1</p> <p>P62</p> <p>Sarcoglycan-Alpha</p> <p>Sarcoglycan-Gamma</p> <p>Spectrin 1</p> <p>UCLH1</p> <p>Utrophin (n-terminus)</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Nerve biopsy on FFPE slides (Formalin fixed paraffin embedded)</p>	<p><u>Neuropathology examinations to assist in clinical investigations</u> (cont'd)</p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p> <p>Demonstration of:</p> <p>Basophilic and eosinophilic structures</p> <p>Collagen</p> <p>Amyloid, elastic fibres</p> <p>Ferric iron</p>	<p>In house documented methods and manufacturer's instructions</p> <p>Documented in house procedures in conjunction with manufacturer's instructions for: Specimen Preparation NP-LAB-SOP-013</p> <p>Tissue Processing: Thermo Scientific Excelsior AS (biopsy processing) Thermo Scientific Excelsior ES (Post mortem processing) NP-LAB-SOP-004 Embedding: Embedding centre TES99 Medite medizintechnik Microtomy: Rotary Microtome – Leica RM2235 Base Sledge Microtome – Leica SM2400 NP-LAB-SOP-005</p> <p>Histochemical Staining Using Manual Techniques</p> <p>Haematoxylin and Eosin NP-LAB-SOP-042</p> <p>Haematoxylin Van Gieson NP-LAB-SOP-047</p> <p>Sirius Red NP-LAB-SOP-049</p> <p>Perl's Prussian blue NP-LAB-SOP-039</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Nerve biopsy</p>	<p><u>Neuropathology examinations to assist in clinical investigations</u> (cont'd)</p> <p>Examination of frozen tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p> <p>Demonstration of:</p> <p>Basophilic and eosinophilic structures</p> <p>Collagen</p> <p>Lipids</p> <p>Fungi, some bacteria, cerebroside and sphingomyelin, sialomucins and neutral mucins, glycogen, starch, elastin, reticulin, some lipofuscins</p> <p>Myelin sheaths</p>	<p>In house documented methods and manufacturer's instructions</p> <p>Documented in house procedures in conjunction with manufacturer's instructions for: Specimen Preparation NP-LAB-SOP-013</p> <p>Cryotomy NP-LAB-SOP-012</p> <p>Cryostat – Leica CM3050S</p> <p>Histochemical Staining Using Manual Techniques</p> <p>Haematoxylin and Eosin NP-LAB-MET-016</p> <p>Haematoxylin Van Gieson NP-LAB-MET-065</p> <p>Oil Red O NP-LAB-MET-075</p> <p>Periodic Acid Schiff and Periodic Acid Schiff/Diastase NP-LAB-SOP-035 &amp; NP-LAB-SOP-034</p> <p>Solochrome Cyanine NP-LAB-SOP-040</p>



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Neuropathology examinations to assist in clinical investigations</u> (cont'd)	In house documented methods and manufacturer's instructions
Nerve Biopsy	Immunohistochemistry of histopathology samples of neurological origin to detect the following:	Manual immunohistochemistry using Vectastain Elite ABC and Biogenex Polymer HRP methods
	B-cell marker	NP-LAB-SOP-007 NP-LAB-MET-010 NP-LAB-MET-015 Incorporating the following antibodies: CD20 (L26)
	Pan T/B cell marker	CD45 (leucocyte common ab)
	Monocytes and macrophages	CD68 (macrophage KP1)
	Plasma cells	CD138
	Proliferating cells	MIB1 (Ki-67)
	Antibody to phosphorylated and unphosphorylated neurofilament,	Neurofilament (pan)
	200 & 70 KDA (phosphorylated)	Neurofilament (phosphorylated)
	T-cell marker	UCLH1
Fresh central nervous system tissue samples.	Intra-operative smears or frozen sectioning for the detection of abnormal cells	Supported by: NP/LAB/SOP/010;NP/LAB/SOP/012 Cryostat – Leica CM3050S Stains – NP-LAB-MET-088; NP-LAB-MET-089; NP-LAB-MET-016
Slides prepared as above	Morphological assessment and interpretation/diagnosis	NP/MGT/SOP/004 NP/MGT/SOP/005 NP/MGT/SOP/007
END		