


Schedule of Accreditation

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United Kingdom Accreditation Service

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

 UKAS MEDICAL 8534 Accredited to ISO 15189:2012	The Newcastle-upon-Tyne Hospitals NHS Foundation Trust	
	Issue No: 009 Issue date: 20 November 2024	
	Department of Cellular Pathology Level 3, New Victoria Wing Royal Victoria Infirmary Queen Victoria Road Newcastle upon Tyne NE1 4LP	Contact: Emma Doran Tel: +44 (0)191 2824445 E-Mail: emma.doran3@nhs.net Website: www.newcastlelaboratories.com
Testing performed by the Organisation at the locations specified below		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details		Activity	Location code
Address Department of Cellular Pathology Level 3, New Victoria Wing Royal Victoria Infirmary Queen Victoria Road Newcastle upon Tyne NE1 4LP	Local contact Mrs Emma Doran	Mortuary Services and Body Store	1



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Site activities performed away from the locations listed above:

Location details	Activity	Location code
Address: Freeman Hospital Freeman Road High Heaton Newcastle upon Tyne NE7 7DN Local contact Mrs Emma Doran	Mortuary Services and Body Store Endobronchial Ultrasound (EBUS) clinic	2
Address: Sir James Spence Peacock Hall Royal Victoria Infirmary Queen Victoria Road NE1 4LP Local contact Mrs Emma Doran	Diagnostic Cytology Neuropathology Specimen dissection	3
Address: Muscle Immunoanalysis Unit Lower Ground Floor Dental Hospital Richardson Road Newcastle upon Tyne NE2 4AZ Local contact Mrs Emma Doran	Muscle histochemistry	4
Address: Wolfson Building Newcastle University Claremont Place Newcastle upon Tyne NE2 4AA Local contact Mrs Emma Doran	Histopathology Special Stains Immunocytochemistry Molecular Pathology Electron Microscopy	5



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS and TISSUES	<u>Examination in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u>	Documented in house methods incorporating manufacturers' instructions where relevant:	
Tissue samples	<u>Histopathology</u>	Tissue processing Documented procedure & manufacturer's instructions using Leica Peloris II & III using , HIML111, HIML146 and HINP023	3 & 5
		Specimen Dissection Manual method using documented procedures in the range HIHD003-116 plus HINP034, HINP054 and HISR080	3
		Decalcification of tissue samples using documented procedure HISR120	
		Tissue embedding using Leica Arcadia embedding centre – HIML012, HIML015 HIEM004	3 & 5
Formalin Fixed Paraffin Embedded Tissue (FFPE) (Resin blocks for ultramicrotomy)		Tissue sectioning including ultramicrotomy Manual methods using manufacturer's instructions for Leica/Thermo fisher Microtomes and HIML016, HIML018, HIML116, HIEM040,	3 & 5



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>Examination in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u> (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant:	
Resin prepared blocks	Examination of cellular structures	Transmission Electron Microscopy using Jeol JEM 1011 transmission electron microscope using in house documented procedures HIEM029 and manufacturer's instructions; HIEM004, HIEM058, HIEM006, HIEM007	5
Fixed tissue samples	Routine staining for identification of basophilic and eosinophilic structures	Routine Automated staining (H&E) Documented procedure & manufacturer's instructions using Dako Coverstainers, HIML137	5
Fixed tissue samples	Special staining to identify the following:	Manual staining by documented procedure HIML043.	5
	Acid Mucins	Alcian Blue (HIML032)	5
	Glycoaminoglycans, Acid mucins	Alcian Blue DPAS (HIML088)	5
	Acid and Neutral mucins	Alcian Blue/PAS (HIML088)	5
	Amyloid	Congo Red (HIML141)	5
	Glycogen Digestion	Diastase PAS (HIML057, CYSL029)	5
Semi thin resin block	Semi thin analysis of nerves	Thionine Blue (HIEM006)	5
	Elastic/Muscle/Connective tissue	Elastic Van Gieson (HIML037)	5



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>Examination in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u> (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant:	
	Plasma cell cytoplasm Mast cell granules Neutrophil granules Eosinophil granules Cytoplasm of erythroid precursors Other cytoplasm	Giemsa pH 5.0 (Bone Marrow trephines- HIML038.1)	5
Fixed tissue samples (cont'd) Unless stated	Gram positive and Gram negative bacteria	Gram (HIML039)	5
	Fungi	Grocott (HIML097)	5
	Special staining to identify the following: (cont'd)	Manual staining by documented procedures listed below	5
	Helicobacter	Heavy Giemsa (HIML038)	5
	Plaques in Alzheimer's	Methenamine Silver (HINP098)	5
	Melanin	Masson Fontana (HIML048)	5
	Mitochondria, myelin of nerves, nemaline rods	Modified Gomori (HIMN041)	5
	Fibrin	MSB (HIML053)	5
	Erythrocytes Muscle/cytoplasm Connective tissue Nuclei	Masson Trichrome (HIML049)	5
	Modified bacilli and atypical bacilli	Modified Ziehl Neelsen (HIML070)	5
Hepatitis B surface antigen, copper associated protein	Orcein / Shikata (HIML056)	5	



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Fixed tissue samples (cont'd) Unless stated	Special staining to identify the following: (cont'd)	Manual staining by documented procedures listed below	
Fresh tissue	Adipose cells	Oil Red O (HIML055)	5
	Fungi/Glycogen/Mucins	PAS (CYSL029, HIML057,)	5
	Glomerular Basement membrane	PASilver (HIML099)	5
	Iron	Perls Iron (HIML046)	5
	Reticulin	Reticulin Gordon Sweets (HIML061)	5
	Copper	Rhodanine (HIML117)	5
	Glomerular Basement membrane	PASilver (HIML099)	5
	Lipid droplets	Sudan Black (HIMN036)	4
	Mast cells	Toluidine Blue (HIML064)	5
	Collagen	Van Gieson (HIML066)	5
	Calcium	Von Kossa (HIML067)	5
	Acid fast tubercle bacteria	Ziehl Neelsen (HIML069)	5



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Fresh muscle samples	Special staining to identify the following:	Enzyme Histochemistry Manual staining by documented procedures listed below	4
Fresh muscle biopsies	Lysosomal storage disorders and vacuolar myopathies.	Acid Phosphatase (HIMN008.0)	4
	Fibre type pattern, fibres devoid of activity	Cytochrome Oxidase (HIMN016.0)	4
	Fibres devoid of cytochrome oxidase activity appear blue.	Combined Cox SDH (HIMN015)	4
	Absent/deficient in exertional myalgia.	Myoadenylate deaminase (HIMN009.0)	4
	Distribution and involvement of fibre types and their subtypes.	ATP pH 4.3 (HIMN011.0)	4
	Fibre type pattern, distribution of mitochondria, myofibrillar disruption.	Nicotinamide Adenine Dinucleotide (HIMN031.0)	4
Fresh tissue samples	Histiocytes, lysosomes, neuromuscular and myotendinous junctions.	Non-specific esterase (HIMN018.0)	4
	Absent in type VII glycogenosis	Phosphofructokinase (HIMN046)	4
	Control for PFK	Aldolase (HIMN049)	4
	Absent in type V glycogenosis (McArdle's disease)	Myophosphorylase A B (HIMN033.0)	4
	Fibre type pattern, fibres with abnormal mitochondria	Succinate Dehydrogenase (HIMN035.0)	4



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Fresh tissue samples (cont'd)	Distribution and involvement of fibre types and their subtypes	ATP pH 4.6 (HIMN011.0)	4
	Immunofluorescence examination for the purposes of clinical diagnosis	Microscopic examination supported by manual labelling of tissue with fluorescent antibodies (using HIIC 156) Cryotomy using Leica Cryostat and documented procedures HIIC155	5
	Immune deposits in renal biopsies	C1Q FITC	5
	Immune deposits in bullous pemphigoid	C3 FITC	5
	Stains fibrinogen (buccal immunofluorescence)	FIBRINOGEN FITC	5
	IgA immunoglobulins (IMF)	IgA FITC	5
	IgG immunoglobulins (IMF)	IgG FITC	5
	IgM deposits (IMF)	IgM FITC	5
	Kappa Light chains (FITC)	KAPPA FITC	5
	Lambda light chains	LAMBDA FITC	5



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Fixed tissue samples	Immunocytochemistry for the identification of:	In house documented procedures & manufacturer's instructions using Ventana Benchmark XT and Ultra system automated ICC stainers HIIC122 & HIIC123	
	Pituitary adenoma	ACTH	5
	Detection of Adenovirus	Adenovirus	5
	Cocktail comprising high- and low-molecular weight cytokeratins.	AE1/AE3	5
	Germ cell tumours and hepatocellular carcinoma.	AFP	5
	Lung AdenoCa with EML4 mutation.	ALK D5F3	5
	Acinar cells of the pancreas and hepatocytes	Alpha-1 antitrypsin	5
	Hepatocellular carcinoma.	Arginase (Liver arginase)	5
	T-cell lymphocytes.	BCL-2	5
	B-cell lymphocytes.	BCL-6	5
	Differentiates adenocarcinoma from mesothelioma.	Ber-EP4	5
	Differentiates BCC from SCC.	BerEp4 and S100 Cocktail	5
	Detects BRAF mutation in melanoma.	BRAFV600E	5
	Breast tumours with apocrine gland features.	BRST-2	5



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Fixed tissue samples (cont'd)	Immunocytochemistry for the identification of: (cont'd)	In house documented procedures & manufacturer's instructions using Ventana Benchmark XT and Ultra system automated ICC stainers HIIC122 & HIIC123	
	Peritubular and glomerular capillaries.	C4d	5
	Tumours of lung, endometrium and ovarian origin.	CA125	5
	Pancreatic disease/tumour.	CA19.9	5
	Medullary thyroid tumours.	Calcitonin	5
	Mesothelioma.	Calretinin	5
	Follicular lymphoma.	CD10	5
	GIST tumours	CD117	5
	Subset of T-cells.	CD123	5
	Epithelium. Normal/malignant plasma cells.	CD138	5
	Monocytes, macrophages, Langerhan's cells.	CD14	5
	Endothelial marker	CD141	5
	Hodgkin's lymphoma.	CD15	5
	B cells and follicular dendritic cells.	CD19	5
	Langerhan's cells	CD1A	5



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Fixed tissue samples (cont'd)	Immunocytochemistry for the identification of: (cont'd)	In house documented procedures & manufacturer's instructions using Ventana Benchmark XT and Ultra system automated ICC stainers HIIC122 & HIIC123	
	Pan-T cell marker.	CD2	5
	Pan B cell marker	CD20	5
	Follicular dendritic cells.	CD21	5
	Follicular dendritic cells.	CD23	5
	Pan—T cell marker.	CD3	5
	Reed Sternberg cells.	CD30	5
	Endothelial cells	CD31	5
	Myeloid cells.	CD33	5
	Endothelial cells.	CD34	5
	Helper T cells.	CD4	5
	Megakaryocytes.	CD42b	5
	T, plasma, myeloma cells.	CD43	5
	Pan-lymphocyte marker.	CD45	5
	T cells, B cells in mantle.	CD5	5
	Neuroendocrine tumour.	CD56	5
	Killer cells.	CD57	5
	Megakaryocytes.	CD61	5



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Fixed tissue samples (cont'd)	Immunocytochemistry for the identification of: (cont'd)	In house documented procedures & manufacturer's instructions using Ventana Benchmark XT and Ultra system automated ICC stainers HIIC122 & HIIC123	
	Macrophages, granulocytes.	CD68K	5
	T cells.	CD7	5
	Identification of nucleated erythroid precursor cells	CD71	5
	Pan B cell marker.	CD79a	5
	Natural killer T cells.	CD8	5
	Neuroectodermal tumour cells.	CD99	5
	Intestinal epithelium.	CDX-2	5
	Adenocarcinoma	CEA (mono)	5
	Adenocarcinoma.	CEA(poly)	5
	Neuroendocrine cells.	Chromogranin	5
	Pancreas.	Chymotrypsin	5
	Bowel epithelia	CK18	5
	GI tract epithelia	CK19	5
	Small bowel / stomach epithelia	CK20	5
	Basal epithelial cells.	CK5/6, CK34Be12, CK14	5



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Fixed tissue samples (cont'd)	Immunocytochemistry for the identification of: (cont'd)	In house documented procedures & manufacturer's instructions using Ventana Benchmark XT and Ultra system automated ICC stainers HIIC122 & HIIC123	
	Glandular / transitional epithelium.	CK5D3	5
	Breast, lung, endometrial adeno Ca.	CK7	5
	Ductal and gland epithelium.	CK8	5
	Broad spectrum epithelial marker.	CKMNF	5
	CMV infection.	CMV	5
	Mantle Cell lymphoma.	CYCD1	5
	Cocktail of melanocyte marker with indicator of proliferation.	KI67/MEL Cocktail	5
	Lymphatic endothelium.	D240	5
	Desmin filaments in muscle.	Desmin	5
	GIST marker.	DOG-1	5
	EBV infection.	EBV	5
	Epithelial marker.	E-Cadherin	5
	Epithelial cells.	EMA	5
	Breast tumours (hormone receptor)	ER	5



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Fixed tissue samples (cont'd)	Immunocytochemistry for the identification of: (cont'd)	In house documented procedures & manufacturer's instructions using Ventana Benchmark XT and Ultra system automated ICC stainers HIIC122 & HIIC123	
	Endothelial cells.	ERG (Ets related gene)	5
	Diagnosis of dermatofibromas.	Factor 13a	5
	Endothelial cells	Factor 8(e)	5
	Pituitary adenoma	Follicle SH	5
	Thyroid carcinoma.	GAL-3	5
	Indicates suitability for Herceptin therapy.	GASTRIC HER2	5
	Peptide hormone gastrin.	GASTRIN	5
	GATA Binding Protein 3	GATA3	5
	Demonstrates astrocytes	GFAP	5
	Urology- Confirmation of yolk sac tumour within germ cell tumour, and choriocarcinoma. Liver- Aid diagnosis of HCC, differentiation from benign lesions and other malignancies	Glypican 3	5
	Cytotoxic T cells	GRANZYME B	5
	Helicobacter Pylorii	H.PYLOR	5
	Mesothelioma	HBME1	5



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Fixed tissue samples (cont'd)	Immunocytochemistry for the identification of: (cont'd)	In house documented procedures & manufacturer's instructions using Ventana Benchmark XT and Ultra system automated ICC stainers HIIC122 & HIIC123	
	Smooth muscle - leiomyomas	H-CALDESMON	5
	Germ cell tumour marker	HCG	5
	Hepatocytes	Hepatocyte	5
	Pituitary adenoma	Human Growth Hormone	5
	Herpes virus – Kaposi's sarcoma	HHV8	5
	Melanocytic cells	HMB45	5
	Herpes simplex virus Type II	HSVII	5
	Astrocytoma/ oligodendroglial tumours	IDH1	5
	IgA immunoglobulins	IgA	5
	IgD immunoglobulins	IgD	5
	IgG immunoglobulins	IgG	5
	IgM immunoglobulins	IgM	5
	Mantle zones / plasma cells	Kappa	5
	Proliferation marker	KI-67	5
	Lambda light chains	Lambda	5
	Lin-28 homolog A	LIN28	5



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	Pituitary adenoma	Luteinising Hormone	5
	Mast cells	MCTryp	5
	Melanocytes/melanomas	MEL A	5
	MSI panel for Lynch syndrome	MLH1	5
	MSI panel for Lynch syndrome	MSH2, MSH6	5
	Germinal centre B cells, plasma cells and activated t cells	MUM-1	5
	Rhabdomyosarcoma and Wilm's tumours	Myogenin	5
	Skeletal and cardiac muscle	Myoglobin	5
	Smooth muscle	Myosin	5
	Axonal marker	Neurofilament	5
	Napsin	Napsin	5
	Germ cell tumours	Oct3/4	5
	HPV marker	P16	5
	Tumour suppressor gene	P53	5
	Basal cell epithelium	P63	5



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Fixed tissue samples (cont'd)	Immunocytochemistry for the identification of: (cont'd)	In house documented procedures & manufacturer's instructions using Ventana Benchmark XT and Ultra system automated ICC stainers HIIC122 & HIIC123	
	Prostatic Intraepithelial neoplasia	PIN Cocktail	5
	Anaplastic large cell lymphomas	P80	5
	Chief cells of parathyroid	Parathyroid Hormone	5
	Parvovirus	Parvovirus	5
	B cells	PAX-5	5
	Cytotoxic T cells	Perforin	5
	Paired-box gene 8	PAX8	5
	Progesterone – steroid hormone receptor	PGR	5
	Placenta	PLAP	5
	Programmed Death 1	PD1	5
	Programmed Death Ligand 1	PDL1	5
	MSI panel for Lynch syndrome	PMS2	5
	Pituitary adenoma	Prolactin	5
	Preferentially expressed antibody in melanoma	PRAME	5
	Prostatic adenocarcinoma	PSA	5



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Fixed tissue samples (cont'd)	Immunocytochemistry for the identification of: (cont'd)	In house documented procedures & manufacturer's instructions using Ventana Benchmark XT and Ultra system automated ICC stainers HIIC122 & HIIC123	
	Prostatic carcinoma and metastases	PSAP	5
	Phosphatase and tensin	PTEN	5
	Prostatic Intraepithelial neoplasia	Racemace	5
	Renal cell carcinomas	RCC	5
	Erythrocytes and precursors	RET40f	5
	Proto-oncogene tyrosine-protein kinase ROS	Ros-1	5
	Nerves, glial cells, melanoma marker	S100	5
	Smooth muscle and tumours	SMA	5
	Melanoma subtypes	SOX 10	5
	Polyoma virus	SV40	5
	Synaptic and neuroendocrine	Synaptophysin	5
	Syphilis	Treponema.Pallidum	5
	TLE Family Member 1	TLE-1	5
	Lymphoblastic leukaemia	TDT	5
	Thyroid follicular carcinoma	Thyroglobulin	5



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>Examination in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u> (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant:	
Fixed tissue samples (cont'd)	Immunocytochemistry for the identification of: (cont'd)	In house documented procedures & manufacturer's instructions using Ventana Benchmark XT and Ultra system automated ICC stainers HIIC122 & HIIC123	
	Renal cell carcinoma subset	Transcription Factor E3	5
	Thyroid/ thyroid tumours	TTF-1	5
	Vascular smooth muscle/fibroblasts/endothelial cells/Langerhan's cells	Vimentin	5
	Varicella Zoster virus	VZV	5
	Glomeruli, proliferating mesothelial cells	WT1(poly)	5
Fresh muscle samples	Assessment of Xp21 muscular dystrophies.	b-dyst	5
	To assess preservation of the plasmalemma in muscle.	b-spec	5
	Diagnosis of Xp21 muscular dystrophies	Dyst C & N	5
	Diagnosis of Emery-Dreifuss muscular dystrophy	Emerin	5
	Diagnosis of limb girdle muscular dystrophies 2C-F	G-sarc	5
	Assessment of muscular dystrophies	Laminin Alpha 2	5
	Assessment of myositis and muscular dystrophies	Utrophin	5



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>Examination in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u> (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant:	
Tissue samples	Demonstration of gene sequences for the purpose of disease diagnosis	In House documented procedure & manufacturer's instructions using the following: Automated in situ hybridisation instruments (Ventana Benchmark XT and Ultra) using HIIC122 & HIIC123	5
	<u>Neuropathology</u>	EBVISH, HER2 dual ISH (Roche) / Chr17 Breast and Gastric as per (HIMP085 and HIMP086) HR-HPV Probe, Kappa Probe, Lambda Probe	
Fresh Tissue (inc. brain, muscle)		In House documented procedure & manufacturer's instructions using the following: Cryotomy using Leica/Thermo Cryostats and documented procedures HISR051, HINP153, HIMN004	3 & 4
Fixed tissue samples	Routine H&E staining for identification of basophilic and eosinophilic structures	Manual staining by documented procedure HINP082	3
	<u>Cytopathology</u>	In House documented procedure & manufacturer's instructions using the following:	
Wet fixed preparations - Body Fluids, urine, CSFs, aspirates, washings, brushings		Processing - Manual methods using documented procedures in the range: CYPL006-008	3



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>Examination in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u> (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant:	
	<u>Cytopathology</u> (cont'd)	In House documented procedure & manufacturer's instructions using the following:	
Air-dried Preparations Body Fluids, CSFs	Detection of abnormal cells	Manual staining of Papanicolau (CYSL028), PAS/DPAS (CYSL029)	3
FNA Wet fixed preparations Breast, Thyroid, Lymph nodes		Automated Papanicolau staining using documented procedures & manufacturer's instructions on the following equipment - Gemini stainer (CYSL036) and BD Totalys Slideprep (CYPL032, CYPL033, CYPL034)	3
FNA and body fluids	May Grunwald Giemsa	Documented procedures & manufacturer's instructions using the Aerospray Haematology 7152 Pro Slide stainer (CYSL059)	3
FNA samples	Rapid on-site evaluation at Endobronchial Ultrasound (EBUS) clinic	Manual preparation and staining using Diff-Quik as detailed in CYSL001	3
Prepared slides	Morphological assessment and interpretation/diagnosis	Diagnostic microscopy using Microscopes (Cell-Path-Med-Trn-08) – used to QC special stains – used to QC IHC slides – used to screen slides for control tissue for IHC – used as a polarizing microscope HIML 141	3, 4 & 5
END			