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ISO 15189:2022

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

NHS Highland

Issue No: 006 Issue date: 17 December 2025

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 CV 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
Tissue samples	<u>Frozen Section Histology Examinations & Touch Preparations to assist in clinical investigations</u>	In House documented procedure & manufacturer's instructions using the following 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 Using AFOS downflow benches



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<p>HUMAN BODY FLUIDS and TISSUES (cont'd)</p> <p>Tissue samples (cont'd)</p>	<p><u>Routine Histopathology examinations to assist in clinical investigations (cont'd)</u></p> <p>Identification of basophilic and eosinophilic structures</p>	<p>In House documented procedure of manual methods using the following</p> <p>Decalcification of tissue sample included in H-SPEC-002 Imaging using Hologenic Faxitron H-SPEC-039</p> <p>Tissue processing Documented procedure & manufacturer's instructions using Thermo Shandon Excelsior AS H-SPEC-003 & H-SPEC-009 & H-SPEC-008.</p> <p>Tissue embedding using Thermo Shandon Histostar H-EMBE-001 & H-EMBE-002</p> <p>Tissue sectioning (Microtomy) Manual method, documented procedure using Leica Microtomes RM2235/RM2125 RT. H-MAIN-001, H-MAIN-002, H-MAIN-008 & H-MAIN-017</p> <p>Routine staining (H&E) Documented procedure & manufacturer's instructions using Leica Autostainer XL and Leica CV 5030 coverslipper and manual methods H-MAIN-001 H-MAIN-010</p> <p><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</p>



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>Special staining of Histopathology examinations to assist in detection of clinical abnormalities</u>	In House documented procedure of manual methods using and Microscopy Manual Methods using documented procedures in series H-STAIN-001
	Acid Fast Tubercle Bacilli	Zeihl Nielson
	Amyloid	Puchtler's Congo Red
	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 Schiffs (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	



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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
	Mycobacterium leprae	Wade-Fite
	Reticulin Fibres	Gordon & Sweet's Reticulin
	Spirochetes	Warthin Starry
	<u>Morphological assessment and interpretation/diagnosis</u>	Microscopy SOP D-CLIN-001 & D-CLIN-002
	<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
	Normal/neoplastic tissue epithelial in origin pan cytokeratin (broad range)	AE1/AE3
	Adenocarcinomas, columnar epithelial cells	Cytokeratin 20
	Anaplastic Large cell Lymphoma's (ALCL's)	ALKinase
	Apoptosis (Cell Death)	PD-1
	B cell follicles	Lambda
	B cell lymphomas, germinal centre derived lymphomas	OCT 02
	B cells	CD20 (CD20cy)
	B cells	CD79a
B Cells	PAX-5	
B cells and plasma cells	Kappa	



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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 Leica Biosystems Bond III Fully automated ICC and ISH stainer
	B cells lymphomas	Bcl-6 Protein
	B cells, follicular lymphomas	Bcl-2
	B cells, plasma cells	Bob-1
	B cells, some T cells	CD23
	B cell lymphomas	CD 19
	Basal cells, filamentous keratins from glandular to stratified squamous, prostate adenocarcinoma	CK, HMW (34BE12)
	Breast carcinoma's expressing HER-2	HER-2
	Breast, Colon, lung and urothelial carcinoma's	P53 (DO-7)
	CEA glycoproteins	CEA
	Cells of mesenchymal origin	Vimentin
	Complement C4d in allograft rejection	C4d
	Cytomegalovirus	Cytomegalovirus
	Cytotoxic T Lymphocytes, Natural Killer cells	Granzyme B
	Embryonic cells in normal tissues and germ tumours	a-1-Fetoprotein
Endothelial cells	CD31 and FVIII	
Epithelial cells	Cytokeratin 14	
Epithelial cells	Cytokeratin 8/18	



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>Immunocytochemistry of Histopathology examinations to assist in detection of clinical abnormalities (cont'd)</u> Epithelial Marker-favours adenocarcinoma Epithelial cells/predominantly adenocarcinomas Endothelial cells/some soft tissue tumours Epithelial cells and smooth muscle in fallopian tube. Wilm's tumour Epithelial cells including ductal and glandular epithelia Erythrocytes Expressed in variety tumours Gastro Intestinal Stromal tumours (GIST) Germ cell tumours, seminomas Granulocytes, reed-Sternberg cells Hairy cell leukaemia cells Herpes Simplex Virus type 1 Hepatocytes Intestinal epithelial cells, colorectal + other adenocarcinomas Kaposi sarcoma cells Langerhans cells Leucocytes Lymphatic vessels	In house documented procedures & manufacturer's instructions using Leica Biosystems Bond III Fully automated ICC and ISH stainer MOC31 BERE4 CD34 Wilm's Tumour (WT1) Cytokeratin 19 GLYCO Cyclin D1 DOG-1 PLAP CD15 (Leu-M1) TRAP HSV1 HEP PAR CDX2 HHV8 CD1a CD45 (LCA) D2-40



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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 MUM1
	Macrophages, monocytes, myeloid cells	CD68 (Routine PG M1)
	Marker for mesotheliomas	Calretinin
	Mature B cells, Follicular dendritic cells	CD21
	Mature B cells, follicular dendritic cells, CALLA	CD10 (CALLA)
	Mature T cells, T cell Lymphomas	CD5
	Melanoma marker	Melan A
	Melanoma, melanocyte differentiation	HMB45
	Mismatch repair protein, Lynch Syndrome	MLH, MSH2, MSH6, PMS2
	Myeloid cells	CD33 Myeloperoxidase
	Natural killer cells, neuroendocrine tissues	CD56 (N-CAM) CD 57
	Neuroendocrine cells	Synaptophysin
	Normal and neoplastic epithelia	Cytokeratin 7
	Normal duct epithelial cells, ductal carcinoma	E-Cadherin
	Normal epithelium, over expression in various cancers	EMA
	Nuclei of cells containing a high level of oestrogen	ER



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>Immunocytochemistry of Histopathology examinations to assist in detection of clinical abnormalities</u> (cont'd) Nuclei of cells showing expression of Progesterone Ovarian epithelial malignancies, seminal vesical carcinoma, anaplastic lymphoma Pan cytokeratin (broad range) Parafollicular 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



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	Smooth muscle cells	Caldesmon
	Smooth muscle cells, myoepithelial cells	SMA
	Soft tissue neoplasms	PACT
	Squamous epithelial cells/Mesotheliomas	CK5
	Stratified squamous epithelium, basal cells and mesotheliomas	Cytokeratin 5/6
	Striated and smooth muscle cells	Desmin
	T & B Lymphocytes, Leukaemias, acute lymphocytic lymphomas	TdT
	T cell Lymphomas	TIA-1
	T cells	CD2 (LFA-2), CD3
	T cells	CD8
	T cells (helper & mature)	CD4
	T cells, Natural killer cells, thymocytes	CD7
	Thyroglobulin containing cells	Thyroglobulin
	Tissues of neuroendocrine origin	Chromogranin A
	TTF-1 found in lung and thyroid (thyroid follicular cells)	TTF-1
V.W. factor in endothelial cells	Factor XIIIa	
Urothelial cells/Breast	GATA	



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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	CD117 (c-kit) 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;- Using Zeiss Axiolab fluorescent microscope documented procedure in S-ICC-008 & S-ICC-011 Leica Biosystems Bond III Fully automated ICC and ISH stainer EBER ISH KAPPA ISH LAMBDA ISH Interpretation of staining pattern Microscopy SOP D-CLIN-001 & D-CLIN-002

END