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

UKAS MEDICAL 9705 Accredited to ISO 15189:2012	Synnovis Analytics LLP
	Issue No: 020 **Issue date:** 01 November 2023

Histopathology **Ground Floor Bessemer Wing** **King's College Hospital** **Denmark Hill** **London** **SE5 9RS**	**Contact: Janet Okafor** **Tel: +44 (0) 203 2994610** **E-Mail: janet.okafor@nhs.net** **Website: www.synnovis.co.uk**

Testing performed by the Organisation at the locations specified

Locations covered by the organisation and their relevant activities

Location details		Activity	Location code
Histopathology Ground Floor Bessemer Wing King's College Hospital	Janet Okafor (as above)	Histopathology Diagnostic Cytopathology Molecular Pathology	KC
Radiology Denmark Wing FNA Clinic King's College Hospital	Janet Okafor (as above)	FNA material/slide preparation Cellularity assessment	KCFNA
Dental Radiology FNA Clinic King's College Hospital	Janet Okafor (as above)	FNA material/slide preparation Cellularity assessment	KCFNA

	Schedule of Accreditation **issued by** **United Kingdom Accreditation Service** 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK
9705 **Accredited to** **ISO 15189:2012**	**Synnovis Analytics LLP** **Issue No:** 020 **Issue date:** 01 November 2023
	Testing performed by the Organisation at the locations specified

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS	Histopathology Preparation and examination to identify or exclude morphological & cytological abnormalities	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	KC
Formalin fixed tissues		Macroanalysis and dissection Manual methods using: LPHIS02 Histopathology Cut-Up LPHIS03 Handling Fresh Lymph Nodes LPHIS07 BMS Cut-UP MEDP01 General guidelines for specimen dissection MEDP02 Handling of Pathological MEDP03 Breast Specimen Dissection SOP MEDP04 Cardio-Pulmonary Specimen Dissection MEDP05 Endocrine Specimen Dissection MEDP06 Gastrointestinal Specimen Dissection MEDP07 Urinary and Male Genital System Specimen Dissection SOP MEDP08 Gynaecological Specimens Dissection SOP MEDP09 Lymphoreticular Specimen SOP MEDP10 Musculo-Skeletal Specimens SOP MEDP11 Perinatal and Paediatric Specimen Dissection SOP MEDP12 Skin Specimen Dissection SOP	KC
		Decalcification Manual method using: LPHIS09 DECALCIFICATION LPHIS29 Decalcification Procedure	KC

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

UKAS
MEDICAL
9705
**Accredited to
ISO 15189:2012**

Synnovis Analytics LLP

Issue No: 020   **Issue date:** 01 November 2023

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	KC
Formalin fixed tissues		Tissue Processing Automated method using: LPHIS23 and Sakura Tissue Tek VIP 6 Sakura Tissue Tek VIP 6 AI	KC
Formalin fixed tissues		Embedding Manual method using: LPHIS10 Tissue embedding and: Sakura Tissue Tek 6 embedding centres	KC
Formalin fixed paraffin embedded (FFPE) tissue		Microtomy Manual method using: LPHIS11 Tissue sectioning and Leica 2235 Leica Histo Core Biocut	KC
Fresh tissue Frozen tissue	Intra-operative diagnosis	Rapid frozen section: Cryotomy and manual Haematoxylin & Eosin (H&E) staining method using: LPHIS19 Using and Defrosting Cryostats and: ThermoScientific NX50	KC

UKAS MEDICAL	
9705 **Accredited to** **ISO 15189:2012**	**Synnovis Analytics LLP** **Issue No:** 020 **Issue date:** 01 November 2023

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	KC
FFPE tissue	Basophilic and eosinophilic tissue structures	<u>Routine Haematoxylin & Eosin (H&E) staining and coverslipping</u> Automated method using: LPHIS12 and: Sakura Prisma Autostainer	KC
		<u>Special staining</u> Manual methods using: LPHIS16 and the following stains:	KC
FFPE tissue (unless otherwise stated)	Detection of the following:		
	Acid mucins (suplhomucins & sialomucins)	Alcian Blue	
	Acid mucins (suplhomucins & sialomucins) Neutral mucins Mixed mucins	Alcian Blue/PAS/diastase	
	Mast cells Acid mucopolysaccharides	Azure A	
	Amyloid	Congo red	
	Elastic and mast cell granules	Elastic Van Gieson (EVG)	
	Mast cells	Giemsa	
	Gram positive and gram negative organisms	Gram's	
	Fungi	Grocott	

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

UKAS
MEDICAL

9705
Accredited to
ISO 15189:2012

Synnovis Analytics LLP

Issue No: 020   **Issue date:** 01 November 2023

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	KC
FFPE tissue (unless otherwise stated)	Detection of the following:	Special staining (cont'd)	KC
	Basophilic and eosinophilic tissue structures	H&E	
	Collagen and muscle	Haematoxylin Van Gieson (HVG)	
	Basement membranes	Jones Methenamine Silver	
	Muscle & fibrin	Masson trichrome	
	Helicobacter pylori & *Helicobacter*-like organisms	Modified Giemsa	
	Fibrin, muscle & connective tissue	Martius, Scarlet, Blue (MSB)	
	Mucin	Southgate's mucicarmine	
	Hepatitis B antigen, elastic fibres and copper associated protein	Orcein	
Frozen sections	Lipids & phospholipids	Oil red O	
	Glycogen and other tissues containing aldehydes	PAS diastase/PAS	
	Haemosiderin & ferric salts	Perls' Prussian Blue	
	Type IV collagen fibres (Reticulin)	Reticulin	
	Mast cells	Toluidine Blue	

UKAS
MEDICAL

9705
**Accredited to
ISO 15189:2012**

Synnovis Analytics LLP

Issue No: 020   **Issue date:** 01 November 2023

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	KC
FFPE tissue	Detection of the following:	Special staining (cont'd)	KC
	Calcium	Von Kossa	
	Mycobacterium tuberculosis	Ziehl-Neelsen	
		Immunohistochemistry Automated methods using: LPICC16 The LEICA Bond III Staining System LPICC17 Leica Bond-III Reagents and: Leica Bond III	KC
FFPE tissue	Detection of the following:	with the following antibodies:	
	BRAC1-associated protein: Acts as a tumour suppressor	BAP1	
	Cell adhesion marker	β-catenin	
	Reacts with BKV infected cells	BK Virus	
	C4d fragment – a marker of antibody-mediated acute renal allograft rejection, detected in the peritubular capillaries	C4d	
	Calcium binding protein	CALRETININ	
	Mantle cell lymphomas	CD5	
	Common B cell marker and follicular dendritic cells	CD19	

UKAS MEDICAL

9705
Accredited to
ISO 15189:2012

Synnovis Analytics LLP

Issue No: 020   **Issue date:** 01 November 2023

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	KC
FFPE tissue	Detection of the following:	Immunohistochemistry Automated, Leica Bond III (cont'd)	KC
	Marker for increased IL-2 expression associated to lymphoid neoplasia: hairy cell leukaemia, T-cell lymphomas and mastocystosis	CD25	
	Endothelial cells but also expressed on human lymphoid and myelopoetic progenitor cells. Useful to identify vascular tumours and characterise leukaemias	CD34	
	NK cells, neurodendocrine cells and derived tumours	CD57	
	Megakaryocytes, platelets. Useful in evaluating the number of megakaryocytes, size and nuclear lobation, abnormal forms in MDS, AML	CD61	
	B cell antigen receptor, found in the majority of acute leukaemias of precursor B cell type, in B cell lines, B cell lymphomas and in some myelomas. Is NOT present in myeloid or T cell lines	CD79a	

UKAS
MEDICAL

9705
Accredited to
ISO 15189:2012

Synnovis Analytics LLP

Issue No: 020   **Issue date:** 01 November 2023

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	KC
FFPE tissue	Detection of the following:	Immunohistochemistry Automated, Leica Bond III (cont'd)	KC
	Expressed by a wide variety of cells, including bone marrow stem cells, germ cells, melanocytes, mast cells and breast epithelium. Useful in differentiating gastrointestinal stromal tumours from Kaposi's sarcoma	CD117	
	High endothelial venules of the tonsil, plasmacytoid dendritic cells, occasional white blood cells in the bone marrow, as well as expressed by a range of other tissues, for example Leydig cells of the testis. Useful in the identification of plasmacytoid dendritic cell neoplasms	CD123	
	Positive in normal colonic mucosa, gastro-intestinal adenocarcinomas. Negative in mesothelioma	CEA	
	Marker for large number of epithelial cells including ductal and glandular	CK19	

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

UKAS
MEDICAL

9705
Accredited to
ISO 15189:2012

Synnovis Analytics LLP

Issue No: 020   **Issue date:** 01 November 2023

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	KC
FFPE tissue	Detection of the following:	Immunohistochemistry Automated, Leica Bond III (cont'd)	KC
	Reacts with the membrane of hairy cell leukaemia cells. Also reacts with endothelial cells, the cytoplasm of some macrophages, some germinal centre cells, mantle zone cells and immunoblasts	DBA44	
	Reacts with 53kD intermediate filament protein in muscle cells. Skeletal, cardiac (Z bands) and smooth muscle cells react as well as tumours of myogenic origin i.e. leiomyo & rhabdomyosarcomas	Desmin	
	Fibrin & fibrinogen fragments D, E, X & Y	Fibrinogen	
	Von Willebrand factor	FVIIIa	
	Apocrine epithelia i.e. glands. Specific marker for breast carcinoma	GCDFP-15	
	Astrocytes, Schwann cells, satellite cells, enteric glial cells & glial tumours	GFAP	
	MHC Class II antigen expressed on monocytes/macrophages, dendritic cells, B cells and activated T cells	HLA-DR	

UKAS
MEDICAL

9705
Accredited to
ISO 15189:2012

Synnovis Analytics LLP

Issue No: 020   **Issue date:** 01 November 2023

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	KC
FFPE tissue	Detection of the following:	<u>Immunohistochemistry</u> Automated, Leica Bond III (cont'd)	KC
	Spiral shaped microaerophilic, gram negative rod (*Helicobacter pylori*)	H.PYLORI	
	Immunoglobulin heavy chain constant region gamma 4	IgG4	
	Polyclonal light chains of kappa type	Kappa	
	Polyclonal light chains of lambda type	Lambda	
	Mast cells (mast cell tryptase)	MCT	
	Myosin heavy chain smooth muscle. Smooth muscle cells, intact myoepithelial cells in breast	MHC-SM	
	Pan cytokeratin that is positive for simple glandular through to stratified squamous epithelia and their derived neoplasms	MNF116/PANC/KER	
	Neurones, neuroendocrine cells and their derived tumours. Some carcinomas, lymphomas & gliomas	NSE	

UKAS MEDICAL

9705
Accredited to
ISO 15189:2012

Synnovis Analytics LLP

Issue No: 020   **Issue date:** 01 November 2023

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	KC
FFPE tissue	Detection of the following:	Immunohistochemistry Automated, Leica Bond III (cont'd)	KC
	Nuclei of B cells in: germinal centre, mantle zone, monocytoid and plasma cells. Used for classification of lymphomas	Oct2	
	Nuclei of embryonic stem cells and germ cells. Useful marker for germ cell tumours	Oct 3/4	
	Parvovirus infected cells	Parvovirus	
	Nuclei of B cells. B cell transcription factor. Used for classification of B-cell lymphomas	PAX5	
	Perinuclear, cytoplasm of activated T-cells, NK cells. Used to help subtype T-cell lymphomas	Perforin	
	Human placental lactogen	PLACTO	
	Nuclear. Mismatch repair proteins, involved in maintaining the integrity of genetic information. Stains all cells that are in the cell cycle. Mutated in families with HNPCC. Forms heterodimers with MLH1.	PMS2	

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

9705
Accredited to
ISO 15189:2012

Synnovis Analytics LLP

Issue No: 020 **Issue date:** 01 November 2023

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	KC
FFPE tissue	Detection of the following:	Immunohistochemistry Automated, Leica Bond III (cont'd)	KC
	Succinate dehydrogenase complex B in muscle. Defects in SDHB are a cause of susceptibility to pheochromocytoma as well as the cause of hereditary paragangliomas and type 4 Cowden-like syndrome	SDHB	
	Endocrine cells, neuroendocrine cells and their derived tumours	Synaptophysin	
	Cytoplasmic granules in cytotoxic T cells, NK cells. Useful in sub-classifying peripheral T-cell lymphomas	TIA1	
	Nuclei of tumour cells. A tumour suppressor gene. Overexpressed in many tumours	P53	
	Wilms Tumour marker	WT1	

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

9705
Accredited to
ISO 15189:2012

Synnovis Analytics LLP

Issue No: 020   **Issue date:** 01 November 2023

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	KC
		Immunohistochemistry Automated methods using: LPICC19 The Ventana Benchmark Ultra System and: Ventana Benchmark Ultra with the following antibodies:	KC
FFPE tissue	Detection of the following:		
	Expressed in several tissues including prostate, skin and oral mucosa	Androgen Receptor	
	Marker for Hairy Cell Leukaemia and certain types of breast and gastric carcinomas	Annexin A1	
	Detects BRAF V600E mutation	BRAF V600E	
	Expressed by T cells and is expressed by the majority of precursor and mature T cell lymphomas and leukaemias.	CD2	
	Preferred marker for T-cells. A polyclonal pan T antibody, occasional T-cell neoplasms	CD3	
	Expressed on T-helper / regulatory T-cells, monocytes, macrophages and dendritic cells	CD4	
	Labels thymocytes & the majority of peripheral T cells. Early marker of T cell commitment	CD7	
	Cytotoxic/suppressor T-cells	CD8	

UKAS
MEDICAL

9705
Accredited to
ISO 15189:2012

Synnovis Analytics LLP

Issue No: 020   **Issue date:** 01 November 2023

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	KC
		Immunohistochemistry Automated methods using: LPICC19 The Ventana Benchmark Ultra System and: Ventana Benchmark Ultra with the following antibodies:	KC
FFPE tissue	Detection of the following:		
	Expressed on cells of lymphoblastic, Burkitt's & Follicle centre cell lymphomas and cells of patients with chronic myelocytic leukaemia (CML). Also expressed on normal cells, i.e. early lymphoid progenitor cells, immature B cells within adult BM & germinal centre B cells within lymphoid tissue. Also expressed in myoepithelial cells (breast), bile canaliculi, fibroblasts & brush border of kidney & gut epithelial cells	CD10	

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

UKAS
MEDICAL

9705
Accredited to
ISO 15189:2012

Synnovis Analytics LLP

Issue No: 020   **Issue date:** 01 November 2023

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	KC
		Immunohistochemistry Automated, Ventana Benchmark Ultra (cont'd)	KC
FFPE tissue	Detection of the following:		
	Neutrophils, dendritic reticulum cells and most glandular epithelium. Cells of the monocyte/macrophage lineage are negative, so too are non-Hodgkins lymphomas. Hodgkins and RS cells are strongly positive, but the lymphocyte predominant type occasionally negative	CD15	
	Pan B-cell marker, also some Reed-Sternberg (RS) cells. Preferred marker for B-cells	CD20	
	Reacts with follicular dendritic cells and mature B cells.	CD21	
	Expressed by B cells in the germinal centres, useful in the differential diagnosis of small B cell lymphomas.	CD23	
	T cell surface glycoprotein, used for identifying Ewing's sarcoma and peripheral neuroectodermal tumours (PNET)	CD99	
	Transcription factor, used for identifying primary and metastatic tumours of the GI tract	CDX2	

9705
Accredited to
ISO 15189:2012

Synnovis Analytics LLP

Issue No: 020   **Issue date:** 01 November 2023

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	KC
		Immunohistochemistry Automated, Ventana Benchmark Ultra (cont'd)	KC
FFPE tissue	Detection of the following:		
	Regulator of growth-related gene transcription. DLBCL, Burkitt's lymphoma and some follicular lymphomas	Cmyc	
	Anaplastic large cell lymphomas, mononuclear HD & RS cells. Will also demonstrate plasma cells. (Outside lymphoid tissue, Ber H2 labels pancreatic acinar cells and occasionally carcinomas derived from these cells)	Ber H2/Ki-1 (CD30)	
	Reacts with cytokeratins 1, 5, 10 and 14, therefore Labelling squamous, ductal and complex epithelia. Useful in the classification of prostatic adenocarcinoma, and the classification of neoplastic tissue as carcinoma of epithelial origin	CK34βE12	
	Demonstrates A component of amyloid	α-amyloid	
	Macrophages, histiocytic lymphomas and some T-cell lymphomas.	α-1-antitrypsin	
	Hepatocellular carcinomas, yolk sac tumours	α-fetoprotein (AFP)	

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	KC
		Immunohistochemistry Automated, Ventana Benchmark Ultra (cont'd)	KC
FFPE tissue	Detection of the following:		
	Expressed in kidney, colon, prostate, stomach, uterus and liver. Useful in classification of prostate adenocarcinomas	AMACR (Racemase)	
	Broad reactivity with epithelial cells. Mesothelial cells are negative	BerEP4	
	Expressed in normal endometrial glands, ovary and cervix. Expressed in ovarian carcinoma	Ca125	
	Positive in C-cells of the thyroid and medullary carcinoma of the thyroid	Calcitonin	
	Regulatory protein in smooth muscle cells. Labels tumours of smooth muscle and myofibroblastic and myoepithelial differentiation	Caldesmon	

UKAS MEDICAL

9705
Accredited to ISO 15189:2012

Synnovis Analytics LLP

Issue No: 020   **Issue date:** 01 November 2023

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	KC
		Immunohistochemistry Automated, Ventana Benchmark Ultra (cont'd)	KC
FFPE tissue	Detection of the following:		
	Reacts with a 34kD polypeptide that interacts with actin, tropomyosin and calmodulin. Useful for staining the myoepithelium. Is also found to be positive in malignant myoepthelioma, pleomorphic adenoma of salivary gland origin, and angiomatoid malignant fibrous histiocytoma	Calponin	
	Cytokeratins 8, 18 & 19. Epithelial and mesothelial cells and derived tumours. Well differentiated squamous tumours negative. Positive for some sarcomas	Cam5.2	
	Positive for cortical thymocytes, Langerhans cells & interdigitating cells. Reacts with a B cell subset and in defining the thymic stage of T cells characteristically associated with leukaemias & lymphomas	CD1a	

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

9705
Accredited to
ISO 15189:2012

Synnovis Analytics LLP

Issue No: 020   **Issue date:** 01 November 2023

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	KC
		<u>Immunohistochemistry</u> Automated, Ventana Benchmark Ultra (cont'd)	KC
FFPE tissue	Detection of the following:		
	Expressed by T cells and cells of myeloid lineage	CD43	
	Expressed on the surface of platelets, monocytes, granulocytes, B cells and at the endothelial intracellular junction. Useful in determining vascular invasion in breast cancer	CD31	
	Expressed by plasma cells, monocytes, activated T cells, NK cells and thymocytes.	CD38	
	All lymphoid cells, variable reaction with macrophages, histiocytes, monocytes. Myeloid cells are unreactive	CD45/LCA	

9705
Accredited to
ISO 15189:2012

Synnovis Analytics LLP

Issue No: 020   **Issue date:** 01 November 2023

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	KC
		<u>Immunohistochemistry</u> Automated, Ventana Benchmark Ultra (cont'd)	KC
FFPE tissue	Detection of the following:		
	A cell adhesion molecule, expressed by most neuroectodermal-derived tissues and their tumours. Also labels NK cells	CD56	
	Macrophages, myeloid cells and histiocytes and their derived neoplasms	CD68	
	Expressed at late stages of B cell differentiation; by normal and malignant plasma cells and lymphoplasmocytoid cells. Also expressed by normal epithelial cells in some tissues	CD138	
	Endocrine cells, neuroendocrine cells and their derived tumours	Chromogranin	
	High molecular weight Cytokeratins 5 and 6. Expressed in epithelial cells: stratified, transitional, complex, mesothelial, and proliferating squamous epithelium. Useful for distinguishing between: SCC and adenocarcinoma, epithelioid mesothelioma and lung carcinoma when used together with a panel of antibodies	CK5/6	

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	KC
		Immunohistochemistry Automated, Ventana Benchmark Ultra (cont'd)	KC
FFPE tissue	Detection of the following:		
	Intermediate filament protein expressed in simple, complex, transitional, ductal and glandular epithelium. Useful in distinguishing metastatic breast and colonic adenocarcinomas	CK7	
	Intermediate filament protein expressed in cytoplasm of basal layer of stratified and non-squamous epithelia. Useful in identifying SCC of the lung, cervix and skin, also BCC	CK14	
	Reacts with gastric and intestinal epithelium, urothelium and Merkel cells. Useful in distinguishing between GI tract and breast adenocarcinomas	CK20	
	Reacts with lymphatic endothelium, lymphangiomas, Kaposi sarcoma. Useful for identifying lymphatic metastases	D240 (PODOPLANIN)	
	Useful in classifying tumours of epithelial origin, but should be used in conjunction with LCA & cytokeratins. May be positive in large cell lymphomas and plasma cells	EMA	

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	KC
		Immunohistochemistry Automated, Ventana Benchmark Ultra (cont'd)	KC
FFPE tissue	Detection of the following:		
	Useful to demonstrate basement membranes in breast carcinomas	Collagen IV	
	Upregulated in mantle cell lymphomas	Cyclin D1	
	Reacts with the plasma membrane of GIST's including PDGRa mutants that do not express KIT	DOG1	
	Transmembrane cell adhesion molecule in epithelial cells. Useful in identifying lobular breast carcinomas	E-Cadherin	
	Transcription factor for cell proliferation, development and differentiation of many tissue types. Seen in breast carcinomas and urothelial carcinomas	GATA-3	
	Enhances basic T cell response. Marker for immunodeficiency	ICOS	
	Melanocyte differentiation marker, used for melanoma identification. Staining with red chromogen	Melan A (Red)	
	ER positive cells	Oestrogen receptor	

UKAS
MEDICAL

9705
Accredited to
ISO 15189:2012

Synnovis Analytics LLP

Issue No: 020   **Issue date:** 01 November 2023

Testing performed by the Organisation at the locations specified			

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	KC
		Immunohistochemistry Automated, Ventana Benchmark Ultra (cont'd)	KC
FFPE tissue	Detection of the following:		
	Paired box gene 8 differential tumour marker for ovarian, thyroid and renal cell carcinoma	PAX8	
	Lymphoma marker	PD1	
	Progesterone, for the diagnosis of PR-positive tumours and prediction of therapeutic response of breast carcinoma	PR	
	Tumour suppressor. Germline mutation or loss in retinoblastoma ans osteosarcoma. Somatic mutations cause various tumours such as lung high grade neuroendocrine carcinomas	RB1	
	Transcription factor of neural crest and peripheral nervous system. Melanoma-associated marker	SOX 10	
	Spirochaete *Treponema pallidum* for diagnosis of syphilis	Spirochaete	

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	KC
		<u>Immunohistochemistry</u> Automated, Ventana Benchmark Ultra (cont'd)	KC
FFPE tissue	Detection of the following:		
	Blood pro-enzyme that reacts with platelets, megakaryocytes, macrophages, dermal dendritic cells, and fibroblast-like mesenchymal or histiocytic cells. Useful in identifying dermatofibromas and malignancies	Factor 8	
	Polypeptide hormone found in G cells of gastric mucosa. Useful in identifying G cell hyperplasia	Gastrin	
	Erythrocytes, erythropoetic cells in bone marrow, diagnosing erythroid leukaemias (AML)	Glycophorin	
	Lytic granules in cytotoxic T-cells and NK cells. Useful in diagnosing NK/T-cell lymphomas and ALCL	Granzyme B	
	Human Herpes Virus type 8 positive cells. Infection likely to cause Kaposi's sarcoma	HHV8	

UKAS
MEDICAL

9705
Accredited to
ISO 15189:2012

Synnovis Analytics LLP

Issue No: 020   **Issue date:** 01 November 2023

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	KC
		<u>Immunohistochemistry</u> Automated, Ventana Benchmark Ultra (cont'd)	KC
FFPE tissue	Detection of the following:		
	Positive on membrane of mesothelial cells. Some adenocarcinomas are positive but show cytoplasmic staining	HBME-1	
	Melonoma marker, labelling intracytoplasmic antigen in melanomas and other tumours with melanocytic differentiation	HMB45	
	Specific for α-chains	IgA	
	Specific for delta-chains	IgD	
	Specific for μ-chains	IgM	
	Epidermal growth factor receptor overexpression in adenocarcinomas of breast and GI tract origin. This is used for predicting the response to anti-EGFR treatment	HER2	
	Specific for gamma chains	IgG	
	Transforming growth factor beta cytokine. Secreted in Sertoli cells of the testis and granulosa cells of ovary	Inhibin	
	Demonstrates proliferating cells in lymphoma and breast tissue	Ki67 (MIB-1)	

UKAS MEDICAL

9705
Accredited to ISO 15189:2012

Synnovis Analytics LLP

Issue No: 020   **Issue date:** 01 November 2023

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	KC
		Immunohistochemistry Automated, Ventana Benchmark Ultra (cont'd)	KC
FFPE tissue	Detection of the following:		
	Macrophages, histiocytic lymphomas	Lysozyme	
	Melanoma marker	Melan A	
	Syncytiotrophoblasts, but also many other normal tissues. Positive in seminomas, but also in other carcinomas.	PLAP	
	Nuclei of plasma cells, germinal centre B cells, activated T cells	Mum-1	
	Found in myelocytes and generally negative for monocytes. Eosinophils & lymphocytes unreactive	Myeloperoxidase	
	Cytoplasmic proteinase in lung adenocarcinomas	Napsin A	
	Positive in neurones, peripheral nerves, some neuroblastomas & some gangliomas	Neurofilament	
	Nuclei and/or cytoplasm of carcinoma cells. Mutated in many tumours. Indicated in HPV infected cells	P16	

UKAS MEDICAL

9705
Accredited to
ISO 15189:2012

Synnovis Analytics LLP

Issue No: 020   **Issue date:** 01 November 2023

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	KC
		Immunohistochemistry Automated, Ventana Benchmark Ultra (cont'd)	KC
FFPE tissue	Detection of the following:		
	Nuclei of cytotrophoblast and stromal cells in placenta. A tumour suppressor gene. Used to help classify hydatidiform moles	P57	
	Nuclei of a variety of tissues: basal cells of normal epithelium in ectocervix, urothelium, oesophagus, and skin. Also basal cells of glands in breast, bronchi and prostate. Myoepithelial cells express this as well	P63	
	Reacts with secretory and ductal epithelium in normal & neoplastic tissue	PSA	
	Melanocytes, Langerhans cells, histiocytes, chondrocytes, lipocytes, skeletal and cardiac muscle, Schwann cells, epithelial and myoepithelial cells of the breast, salivary and sweat glands, glial cells. Useful in identifying melanomas and other tumours	S100	
	Positive in myoepithelial cells. Reacts with smooth muscle & myoepithelial cells	SMA	

9705
Accredited to
ISO 15189:2012

Synnovis Analytics LLP

Issue No: 020   **Issue date:** 01 November 2023

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	KC
		<u>Immunohistochemistry</u> Automated, Ventana Benchmark Ultra (cont'd)	KC
FFPE tissue	Detection of the following:		
	Nuclei of mantle cell lymphoma cells	SOX-11	
	Lymphoblastic leukaemias & lymphoblastic lymphomas	TdT	
	Positive in thyroid epithelium, thyroid tumours & follicular adenoma	Thyroglobulin	
	Thyroid Transcription factor - nuclear: positive in lung adenocarcinomas, thyroid tumours	TTF1	
	Intermediate filament protein (57kD) of mesenchymal cells, including lymphoid, endothelial, fibroblasts & smooth muscle. A number of tumours co-express vimentin and cytokeratin, e.g. thyroid carcinomas, mixed tumours of salivary gland and some renal carcinomas. Co-expression of desmin & vimentin has been reported in rhabdos, alveolar soft tissue sarcomas and leiomyosarcomas	Vimentin	

UKAS
MEDICAL
9705
Accredited to
ISO 15189:2012

Synnovis Analytics LLP

Issue No: 020   **Issue date:** 01 November 2023

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	KC
FFPE tissue	Fine nerves in the mucosal lamina propria as well as any submucosal ganglion cells/ medium sized nerves cut transversely	Enzyme Histochemistry Manual method using: LPEH01 Acetyl Cholinesterase	KC
Slides prepared in-house from sample types listed above	Morphological assessment and interpretation/diagnosis	Microscopy (qualitative analysis) In-house procedures: LIAD03 – Quality Control LPHIS16 – Quality checking of cases using: Brightfield microscopes	KC

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

9705
Accredited to
ISO 15189:2012

Synnovis Analytics LLP

Issue No: 020   **Issue date:** 01 November 2023

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Molecular Pathology Detection of nucleic acid sequence/variants listed	Examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	KC
FFPE tissue		DNA extraction Automated using: CMP021 and: Qiagen QiaCube	KC
DNA extracted in-house		DNA concentration measurement using: LPAD13 LIAD16 and: Life Technologies QubitFluorometer	KC
DNA extracted in-house		DNA amplification by Polymerase Chain Reaction (PCR) using: SOP: see tests and thermocyclers: Applied Biosystems Veriti Applied Biosystems Step One Plus Eppendorf Nexus Gradient Techne Prime	KC

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Detection of nucleic acid sequence/variants listed (cont'd)	Examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	KC
Amplified DNA	MLH1	Pyrosequencing using: CMP14 and: Qiagen Pyrosequencer Q24	KC
cDNA	IGHV mutation status in CLL	Next generation sequencing using: LPAD25 and: LymphoTrack kit (Invivoscribe), MiSeq and LymphoTrackDxMiSeq software	KC

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

UKAS
MEDICAL

9705
Accredited to
ISO 15189:2012

Synnovis Analytics LLP

Issue No: 020   **Issue date:** 01 November 2023

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
Amplified DNA	Clonality Identity analysis IGH & TCR gene rearrangement	<u>Fragment length analysis</u> using: CMP07 and: Applied Biosystems 3500xl Genetic Analyser	KC
		<u>Chromogenic In-situ hybridisation (CISH)</u> Automated methods using: LPICC16 The Leica Bond III Staining System LPICC17 Leica Bond-III Reagents CMP10 and: Leica Bond III with the following RTU probes:	KC
FFPE tissue (excluding samples requiring decalcification)	Detects encoded RNA present in both latent & lytic EBV infection	EBER	
	Infiltrative lymphocytes, T cells, melanonas and thymus tumours	Kappa	
	Infiltrative lymphocytes, T cells, melanonas, brain tumours and thyroid tumours	Lambda	

UKAS MEDICAL 9705 Accredited to ISO 15189:2012	**Synnovis Analytics LLP** **Issue No:** 020 **Issue date:** 01 November 2023

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Detection of nucleic acid sequence/variants listed (cont'd)	Examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	KC
		Fluorescent In-situ hybridisation (FISH) Automated methods using: LPICC16 The Leica Bond III Staining System LPICC17 Leica Bond-III Reagents CMP10 and: Leica Bond III with the following RTU probes:	KC
FFPE tissue (excluding samples requiring decalcification)	Detection of the following:		
	Alk gene translocation in lung. Anaplastic lymphoma	ALK1	
	Cmyc gene translocation in lymphoma t(8:14)	CMYC	
	Bcl2 translocation in B cell lymphoma, t(14;18). Upregulated in follicular, high grade B-cell & T-cell, lymphoblastic and anaplastic large cell lymphomas. Negative in reactive follicular hyperplasia	BCL2	
	Bcl6 translocation in diffuse large b cell lymphoma	BCL6	
	Her2	Her2	
FFPE tissue		FISH Manual methods using: CMP10 and probes:	KC
	CCDN1	CyclinD-1	

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	Diagnostic cytology Preparation and examination of cellular material to identify or exclude cytological abnormalities	Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	

Body fluids:
  Cerebrospinal fluid (CSF)
  Urine
  General body fluids
  Brushings (Bronchial, gastric, oesophageal, duodenal etc.)
  Skin Scrapings
  Imprints
  Fine Needle Aspirations
  Respiratory Samples (Broncho alveolar lavage (BAL), Brushings, washings and sputum)
		Preparation/centrifugation
		In-house procedures:
		CPCK-COP-1 Cytology Health and Safety
		CPCK-SOP-2 Non-Gynae Preparation
		CPCK-SOP-8 FNA
		in conjunction with manufacturer's instructions using:
		Thermo Shandon Cytospins 3 & 4
		Heraeus Megafuge 1.0 & Labfuge 400
		Hologic T2000 processor
			KC

		Papanicolaou staining Automated/manual using in-house procedures: CPCK-SOP-3 Staining Methods in conjunction with manufacturer's instructions using: Thermo Shandon Varistain Gemini	KC
	Red & white blood cells	Hemacolor staining Automated/manual using in-house procedures: CPCK-SOP-1 Non-Gynae Processing in conjunction with manufacturer's instructions using: Thermoshandon Varistain Gemini	KC
Slides prepared in-house from sample types listed above	Morphological assessment and interpretation/diagnosis	Microscopy (qualitative analysis) In-house procedures: CPCK-SOP- 5 Cytology Quality CPCK-SOP- 6 Winpath User Instructions using: Brightfield microscopes	KC

Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
HUMAN TISSUES AND FLUIDS (cont'd)	<u>Diagnostic cytology</u> Preparation and examination of cellular material to identify or exclude cytological abnormalities	Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
Fine needle aspiration (FNA)	Cellularity assessment (sample adequacy confirmation) followed by subsequent processing and analysis in the Cytopathology Laboratory (KC)	<u>Material/slide preparation followed by microscopy</u> Manual methods using: CPCK-SOP-8 FNA and: Brightfield microscopes	KCFNA
	END		